

US3292023 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:26:49

All time stamps listed in this document are displayed in GMT

US3292023

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 18:00:29

Generated On: 09 Jun 2021 16:26:49

[Participant ID](#)

US3292023

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

US3292023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3292023

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3292023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3292023

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	INTOLERANT TO ARICEPT
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	SEASONAL ALLERGY: MOUNTAIN CEDAR
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3292023

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	SEASONAL ALLERGY: MOLD
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292023

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1958
Start Year (derived)	1958
Stop Month and Year (derived)	JAN 1958
Stop Year (derived)	1958

US3292023

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1958
Start Year (derived)	1958
Stop Month and Year (derived)	JAN 1958
Stop Year (derived)	1958

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	TONSILITIS
Start date (dd MMM yyyy)	UN UNK 1946
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 1946
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1946
Start Year (derived)	1946
Stop Month and Year (derived)	JAN 1946
Stop Year (derived)	1946

US3292023

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1946
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 1946
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1946
Start Year (derived)	1946
Stop Month and Year (derived)	JAN 1946
Stop Year (derived)	1946

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	KNEE REPLACEMENT - LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	KNEE SURGERY - LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	BACK SURGERY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	SURGERY TO PENIS
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	KIDNEY SURGERY - REMOVE BENIGN SPOT ON KIDNEY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	STENT PLACEMENT
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	PEYRONIES PLAQUE SURGERY
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	BILATERAL GLACOMA
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	TYPE I DIABETES
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	DEPRESSION
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 (18)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	ATOPIC DERMITIS ON FACE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	HYPOTHYROID
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	DIABETIC PERIPHERAL NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	KNEE PAIN
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

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

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	BILATERAL CARTILAGE BUILDUP IN KNEES
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	FRACTURED BACK
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	PEYRONIE'S PLAQUE
Start date (dd MMM yyyy)	UN UNK 1982
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

US3292023

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Condition	INSULIN PUMP
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3292023

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:37
Height (xxx.x)	182.1 cm
Weight (xxx.x)	70.5 kg
BMI (xxx.x)	21.26029 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)	

US3292023

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:00:42

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184711

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

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)	04 AUG 2020
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:37
Temperature (xxx.x)	35.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

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)	04 AUG 2020
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:33
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292023

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

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.

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

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) 04 AUG 2020

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

Treatment Date and Time (derived) 04 AUG 2020 16:00

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

US3292023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 AUG 2020
Collection time (00:00-23:59)	15:00 (24 HR)
Collection date and time (derived)	04 AUG 2020 15:00

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:25	04 AUG 2020 15:25
Nasopharyngeal Swab 2	No		

US3292023

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

04 AUG 2020 16:39

PC Open Date & Time

04 AUG 2020 16:20

PC Close Date & Time

04 AUG 2020 18:50

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 AUG 2020 19:45

PC Close Date & Time

05 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

07 AUG 2020 09:02

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

97.3 °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

07 AUG 2020 22:20

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 21:43

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

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

09 AUG 2020 20:45

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

97.0 °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

10 AUG 2020 22:41

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

04 AUG 2020 16:41

PC Open Date & Time

04 AUG 2020 16:20

PC Close Date & Time

04 AUG 2020 18:50

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

04 AUG 2020 19:45

PC Close Date & Time

05 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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 ☐

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

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

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

Yes ☐

No ☐

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

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

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

07 AUG 2020 09:05

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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 ☐

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

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

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

Yes ☐

No ☐

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

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

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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 ☐

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

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

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

Yes ☐

No ☐

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

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

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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 ☐

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

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

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

Yes ☐

No ☐

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

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

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

10 AUG 2020 22:43

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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 ☐

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 16:43
PC Open Date & Time	04 AUG 2020 16:20
PC Close Date & Time	04 AUG 2020 18:50

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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 ☐

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 AUG 2020 19:45

PC Close Date & Time

05 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

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 ☐

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

Yes ☐

PC Time stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

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EAB) (1725)

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 09:06
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

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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US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 22:22
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

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EAB) (1725)

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 21:45
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

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)

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:48
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

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)	1 SEP 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:55
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

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)	1 SEP 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:26
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3292023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 12:47 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 12:47

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

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	12:17 (24 HR)
Collection date and time (derived)	1 SEP 2020 12:17

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	01 SEP 2020 12:25
Nasopharyngeal Swab 2	No		

US3292023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

98.3 °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

01 SEP 2020 13:30

PC Open Date & Time

01 SEP 2020 13:07

PC Close Date & Time

01 SEP 2020 15:37

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	01 SEP 2020 22:00
PC Open Date & Time	01 SEP 2020 16:32
PC Close Date & Time	02 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

99.3 °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

02 SEP 2020 23:00

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

04 SEP 2020 00:43

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

97.6 °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

04 SEP 2020 23:12

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 23:50

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

96.6 °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

06 SEP 2020 21:55

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

97.6 °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

07 SEP 2020 22:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

01 SEP 2020 13:31

PC Open Date & Time

01 SEP 2020 13:07

PC Close Date & Time

01 SEP 2020 15:37

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

01 SEP 2020 22:03

PC Open Date & Time

01 SEP 2020 16:32

PC Close Date & Time

02 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

02 SEP 2020 23:02

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

04 SEP 2020 00:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

04 SEP 2020 23:14

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

05 SEP 2020 23:51

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

06 SEP 2020 21:56

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

07 SEP 2020 22:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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 ☐

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 13:32
PC Open Date & Time	01 SEP 2020 13:07
PC Close Date & Time	01 SEP 2020 15:37

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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 ☐

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 22:05
PC Open Date & Time	01 SEP 2020 16:32
PC Close Date & Time	02 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

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 ☒

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 23:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 00:46
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

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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US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 23:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

120 of 2324

EAB) (1725)

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 23:52
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

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)

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

124 of 2324

EAB) (1725)

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:11
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3292023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT3

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 13:59
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

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.

US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	14:29 (24 HR)
Collection date and time (derived)	29 SEP 2020 14:29

US3292023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:42

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 OCT 2020 14:42:44
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 11:30:39

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

20 OCT 2020 14:30:50

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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	04 NOV 2020 16:05:04
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 05:18:39

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 17:50:15

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 10:47:39

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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 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	06 DEC 2020 07:56:52
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3292023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:30

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:30

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

THREE ATTEMPTS MADE TO
CONTACT SUBJECT; NO
ANSWER.

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:00:41

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 14:09:18

Generated On: 09 Jun 2021 16:26:49

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

SUBJECT HAS DIED.

If Contact Not Made, please provide Comments

US3292023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:09:18

Generated On: 09 Jun 2021 16:26:49

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3292023

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:26:49

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3292023

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

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3292023

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

Form: Unblinding

Generated On: 09 Jun 2021 16:26:49

Date of updated informed consent (<i>dd MMM yyyy</i>)		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
Was the participant unblinded?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5	<input type="checkbox"/>
	Amendment 6 or later	<input type="checkbox"/>
Date of unblinding (<i>dd MMM yyyy</i>)		
Participant randomization assignment	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
Actual Dose 1	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Actual Dose 2	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Will participant receive mRNA-1273?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Placebo Only Flag		
Continuing with mRNA-1273		

US3292023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3292023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:26:49

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00 - 23:59*)

Collection Date and Time (derived)

US3292023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 18:00:30

Generated On: 09 Jun 2021 16:26:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:45:38

Generated On: 09 Jun 2021 16:26:49

AEID	USA-US072-2020-MRNA-1273-P30 1000007
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)	22 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)	26 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	26 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:45:38

Generated On: 09 Jun 2021 16:26:49

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	

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:45:38

Generated On: 09 Jun 2021 16:26:49

PATIENT CONTACTED STAFF TODAY, 27OCT2020, TO STATE THAT HE HAD BEEN HOSPITALIZED RECENTLY DUE TO DIABETIC KETOACIDOSIS. ON THURSDAY, 22OCT2020, PATIENT STATES THAT HE WAS NOT FEELING WELL DUE TO AN INSULIN PUMP THAT WAS NOT FUNCTIONING CORRECTLY. HE STATES THAT HE HAD BEEN WAITING FOR A REPLACEMENT THAT WAS OVERDUE FOR DELIVERY. PATIENT STATES THAT HE HAD CHECKED HIS BLOOD SUGAR, WHICH HAD BEEN REGISTERING BETWEEN 500 AND 700. THE LOWEST READING REGISTERED AT 468. AFTER REALIZING THAT HIS LEVELS WOULD NOT DROP TO NORMAL LEVELS, HE CONTACTED EMS AND WAS TRANSPORTED TO A LOCAL HOSPITAL. UPON BEING EVALUATED BY ER PHYSICIANS, THE PATIENT WAS STARTED ON AN INSULIN DRIP. THE PATIENT WAS NOT ABLE TO REMEMBER ANY OTHER MEDICATIONS THAT HE MAY HAVE BEEN GIVEN. PATIENT WAS DISCHARGED IN STABLE CONDITION ON 26OCT2020. MEDICAL RECORDS WILL BE REQUESTED AS SOON AS POSSIBLE. NO FURTHER INFORMATION AVAILABLE AT THIS TIME.

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

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:45:38

Generated On: 09 Jun 2021 16:26:49

AEID

Adverse event

TOOTH 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)

27 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 NOV 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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:45:38

Generated On: 09 Jun 2021 16:26:49

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:45:38

Generated On: 09 Jun 2021 16:26:49

AEID	USA-US072-2021-MRNA-1273-P30 1000014
Adverse event	END STAGE CONGESTIVE HEART FAILURE
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)	19 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	20 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	184 of 2324

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:45:38

Generated On: 09 Jun 2021 16:26:49

Number of Days in ICU	32
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 checked="" type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:45:38

Generated On: 09 Jun 2021 16:26:49

80 YEAR OLD MAN WITH TYPE
1 DIABETES ON INSULIN PUMP
INITIALLY ADMITTED ON
12/19/2020 WITH DKA, LACTIC
ACIDOSIS, HYPERKALEMIA,
AKI, SEVERE SEPSIS CRITERIA
AS WELL AS FEMUR FRACTURE
AFTER FALL PRIOR TO THIS
ADMISSION. ON 12/20, HE THEN
DEVELOPED ACUTE
HYPOXEMIC RESPIRATORY
FAILURE AND CARDIOGENIC
SHOCK DUE TO STEMI AND
FOUND TO HAVE SEVERELY
DEPRESSED EF OF 20% DUE TO
ACUTE SYSTOLIC
CHF/DILATED
CARDIOMYOPATHY. NO
IMPROVEMENT IN MENTATION
AND FAILED SWALLOW STUDY
DUE PERSISTENT AMS, ALSO
WITH PERSISTENT
LEUKOCYTOSIS W/O CLEAR
SOURCE DESPITE AGGRESSIVE
IV ABX/ANTIVIRALS. OVERALL
HOSPITAL COURSE DISCUSSED
WITH SON TO INCLUDE NO
IMPROVEMENT IN PATIENT'S
MENTAL STATUS. HOSPICE
DISCUSSED. CONSENT FOR
HOSPICE SIGNED ON 1/19/2021.
TRANSFERRED TO HOSPICE
1/20/2021 WITH TERMINAL END
STAGE CONGESTIVE HEART
FAILURE. PATIENT PASSED ON
23JAN2021.

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)	1

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 18:00:30

Generated On: 09 Jun 2021 16:26:49

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

Yes ☒

No ☐

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

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE

Dose per administration 50

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

If dose unit is Other, specify MCG

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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	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 2016	
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	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 2016	
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 60

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication DIABETIC PERIPHERAL
NEUROPATHY

Dose per administration 300

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2013	
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 (5)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication TYPE 1 DIABETES

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

AC

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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 175

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication LISINOPRIL

Prophylaxis Yes ☒
No ☐

Indication KIDNEY DISEASE PREVENTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	
	No <input type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication COMBIGAN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL GLAUCOMA

Dose per administration 3

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

If dose unit is Other, specify DROPS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 2007	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication ROCKLATAN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL GLAUCOMA

Dose per administration 3

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

If dose unit is Other, specify DROPS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 2007	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication LATANOPROST 0.005%

Prophylaxis Yes ☐
No ☒

Indication BILATERAL GLAUCOMA

Dose per administration 2

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

If dose unit is Other, specify DROPS

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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 2007	
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 (11)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE PAIN

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 (11)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication ERGOCALCIFEROL

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 1.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☒
No ☐

Indication DENTAL INFECTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	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 2016	
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 (14)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication TRIAMCINOLONE 0.025%

Prophylaxis Yes ☐
No ☒

Indication FACIAL ATOPIC DERMATITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication GLUCOSE TABLETS

Prophylaxis Yes ☐
No ☒

Indication TYPE 1 DIABETES

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	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 1999	
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 (16)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	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)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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Name of Medication DEXTROSE 5% IN WATER

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 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)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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Name of Medication INSULIN REGULAR 100 UNITS +
SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 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)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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Name of Medication INSULIN REGULAR HUMAN
RECOMB 100 UNITS/ML

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 (19)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication SODIUM CHLORIDE 0.45% +
SODIUM BICARBONATE 8.4% 50
MEQ

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 16:07:15

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 2000

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 (21)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication END STAGE CONGESTIVE
HEART FAILURE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 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)		19 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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☐
No ☒

Indication END STAGE CONGESTIVE
HEART FAILURE

Dose per administration 2.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 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)	19 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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication END STAGE CONGESTIVE
HEART FAILURE

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 ☐

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) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	UN 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)	UN JAN 2021	
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication END STAGE CONGESTIVE
HEART FAILURE

Dose per administration 3.375

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
30 NOV 2020	TOOTH EXTRACTION	Adverse Event	

US3292023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:26:49

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

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

Date of study discontinuation/completion (dd MMM yyyy) 24 JAN 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input checked="" type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 24 JAN 2021

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2020-MRNA-1273-P301000007
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)	2

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2020-MRNA-1273-P301000007
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)	2
Date of submission (Pre-filled from custom function)	28/OCT/2020 13:21
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

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 16:07:15

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2020-MRNA-1273-P301000007
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)	2
Date of submission (Pre-filled from custom function)	25/MAR/2021 10:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 15:45:41

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 15:45:41

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/FEB/2021 15:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 15:45:41

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/FEB/2021 15:23
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

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 15:45:41

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/MAR/2021 06:48
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

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 15:45:41

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/MAR/2021 12:04
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

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 15:45:41

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/MAR/2021 10:26
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

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Apr 2021 15:45:41

Generated On: 09 Jun 2021 16:26:49

SAEID	USA-US072-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/APR/2021 11:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292023 (Prod: Clinical Trials of Texas, Inc)

US3292023

Form: Participant Creation

Generated On: 09 Jun 2021 16:26:49

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:00:57
User entered 'US3292023'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:49:09

US3292023

Form: Participant Creation

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:08:56

US3292023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:49:10

US3292023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Clinic (Clinic)'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:08:56

US3292023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'SCRN'	System	04 Aug 2020 21:08:56

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered (b) (6) 1940'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:49:11

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	06 Aug 2020 18:37:57
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 18:37:57
User opened query 'Age does not fit Date of Birth.' (Site from System).		06 Aug 2020 18:32:12
User entered '65'		06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'YEARS'	System	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '80'	System	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Male (M)' reason for change: Data Entry Error	(b) (4)	06 Aug 2020 18:37:57
User entered 'Female (F)'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error	(b) (4)	06 Aug 2020 18:37:57
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'l'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: New Information	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Nov 2020 15:59:48
User entered '4 Aug 2020'	Nathan Cortez (b) (4)	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Aug 2020'	System	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2020'	System	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Amendment 1 (1)'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:49:10

US3292023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'l'	System	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:26:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:43:40

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Drug intolerance, LLT: Drug intolerance - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 07:56:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 07:56:13
Data point term sent to Coder	System	06 Aug 2020 18:49:19
User entered 'Intolerant to Aricept'	(b) (4), (b) (6)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2013'	(b) (4), (b) (6)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2013'	System	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2013'	System	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 14:31:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 14:31:03
Data point term sent to Coder	System	06 Aug 2020 18:51:26
User entered 'Seasonal allergy: mountain cedar'	(b) (4), (b) (6)	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1990'	(b) (4), (b) (6)	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1990'	System	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1990'	System	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Mycotic allergy, LLT: Allergy to molds - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 22:42:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 22:42:43
Data point term sent to Coder	System	06 Aug 2020 18:52:28
User entered 'Seasonal allergy: mold'	(b) (4), (b) (6)	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1990'	(b) (4), (b) (6)	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1990'	System	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1990'	System	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 18:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 18:58:20
Data point term sent to Coder	System	06 Aug 2020 18:57:42
User entered 'Appendectomy'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1958'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1958'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1958'	System	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1958'	System	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1958'	System	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1958'	System	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 18:59:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 18:59:14
Data point term sent to Coder	System	06 Aug 2020 18:58:43
User entered 'Appendicitis'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1958'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1958'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1958'	System	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1958'	System	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1958'	System	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1958'	System	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Aug 2020 19:01:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:01:25
Data point term sent to Coder	System	06 Aug 2020 19:00:47
User entered 'Tonsilitis'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1946'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1946'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1946'	System	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1946'	System	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1946'	System	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1946'	System	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 19:03:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 19:03:17
Data point term sent to Coder	System	06 Aug 2020 19:01:48
User entered 'Tonsillectomy'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1946'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1946'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1946'	System	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1946'	System	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1946'	System	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1946'	System	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:37:58
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updatedc' (Site from DM).	Dawn Killian (b) (4)	16 Sep 2020 19:18:01
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:55:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee total replacement - version MedDRA\23.0.	Coder Import (b) (4)	09 Aug 2020 00:46:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Aug 2020 00:46:27
Data point term sent to Coder	System	06 Aug 2020 19:01:50
User entered 'Knee replacement - left knee'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2009'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2009'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2009'	System	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2009'	System	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2009'	System	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2009'	System	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:38:12
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	16 Sep 2020 19:20:03
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:55:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 00:46:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 00:46:27
Data point term sent to Coder	System	06 Aug 2020 19:02:55
User entered 'Knee surgery - left knee'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2007'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2007'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2007'	System	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2007'	System	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2007'	System	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2007'	System	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:38:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 19:22:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 19:22:46
Data point term sent to Coder	System	16 Sep 2020 19:21:23
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	16 Sep 2020 19:21:12
Coding entries removed.	Dawn Killian (b) (4)	16 Sep 2020 19:20:52
User entered 'BACK SURGERY' reason for change:	Dawn Killian (b) (4)	16 Sep 2020 19:20:52
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:55:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 00:36:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 00:36:09
Data point term sent to Coder	System	06 Aug 2020 19:04:58
User entered 'Back surgery (broken)'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1990'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1990'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1990'	System	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1990'	System	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1990'	System	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1990'	System	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:38:30
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	16 Sep 2020 19:23:40
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:56:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Penile therapeutic procedures, PT: Penile operation, LLT: Penile operation - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 13:20:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 13:20:41
Data point term sent to Coder	System	06 Aug 2020 19:04:59
User entered 'Surgery to penis'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1988'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1988'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1988'	System	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1988'	System	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1988'	System	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1988'	System	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Renal stone removal, LLT: Renal stone removal - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 21:59:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 21:59:51
Data point term sent to Coder	System	06 Aug 2020 19:06:01
User entered 'Kidney surgery - remove benign spot on kidney'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2006'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2006'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2006'	System	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2006'	System	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2006'	System	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2006'	System	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:39:04
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	16 Sep 2020 19:24:59
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:56:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 19:08:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 19:08:11
Data point term sent to Coder	System	06 Aug 2020 19:07:06
User entered 'Stent placement'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2012'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 2012'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2012'	System	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2012'	System	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2012'	System	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2012'	System	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Penile therapeutic procedures, PT: Penile operation, LLT: Penile operation - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	25 Nov 2020 06:32:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:32:07
Data point term sent to Coder	System	06 Aug 2020 19:08:10
User entered 'Peyronies plaque surgery'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1982'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'un UNK 1982'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1982'	System	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1982'	System	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1982'	System	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1982'	System	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per DM CLR: Please update the condition to include the laterality of Glaucoma (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Sep 2020 11:39:14
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 08:02:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 08:02:02
Data point term sent to Coder	System	16 Sep 2020 19:28:41
Query 'Per DM CLR: Please update the condition to include the laterality of Glaucoma (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Dawn Killian (b) (4)	16 Sep 2020 19:28:04
' answered with 'updated' (Site from DM).		
Coding entries removed.	Dawn Killian (b) (4)	16 Sep 2020 19:27:51
User entered 'bilateral GLACOMA' reason for change: Data Entry Error	Dawn Killian (b) (4)	16 Sep 2020 19:27:51
User opened query 'Per DM CLR: Please update the condition to include the laterality of Glaucoma (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	15 Sep 2020 06:56:32
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 19:22:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 19:22:42

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	18 Aug 2020 17:52:35
User entered 'glacoma'	Dawn Killian (b) (4)	18 Aug 2020 17:51:53
	(b) (4)	

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2007'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2007'	System	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2007'	System	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type I diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Aug 2020 19:22:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:22:41
Data point term sent to Coder	System	18 Aug 2020 17:52:35
User entered 'Type I Diabetes'	Dawn Killian (b) (4)	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 1999'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1999'	System	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1999'	System	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
Data point term sent to Coder	System	18 Aug 2020 17:53:38
User entered 'depression'	Dawn Killian (b) (4)	18 Aug 2020 17:52:48

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2017'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:52:48

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2017'	System	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2017'	System	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per DM CLR: Please specify the location of Atopic Dermatitis. 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)	29 Sep 2020 11:40:34
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Atopic dermatitis - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 07:58:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 07:58:51
Data point term sent to Coder	System	16 Sep 2020 19:30:45
Query 'Per DM CLR: Please specify the location of Atopic Dermatitis. 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)	16 Sep 2020 19:30:14
Coding entries removed.	Dawn Killian (b) (4)	16 Sep 2020 19:29:59
User entered 'ATOPIC DERMITIS on face' reason for change: Data Entry Error	Dawn Killian (b) (4)	16 Sep 2020 19:29:59
User opened query 'Per DM CLR: Please specify the location of Atopic Dermatitis. 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)	15 Sep 2020 06:56:47
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Atopic dermatitis - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 19:43:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 19:43:37
Data point term sent to Coder	System	18 Aug 2020 17:53:40

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
User entered 'atopic dermatitis'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2009'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2009'	System	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2009'	System	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:47
Data point term sent to Coder	System	18 Aug 2020 17:53:38
User entered 'hypothyroid'	Dawn Killian (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2010'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2010'	System	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2010'	System	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
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)	18 Aug 2020 19:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
Data point term sent to Coder	System	18 Aug 2020 17:54:41
User entered 'diabetic peripheral neuropathy'	Dawn Killian (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2013'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2013'	System	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2013'	System	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per DM CLR: Please update the condition to include the laterality of Knee Pain (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Sep 2020 11:39:52
' (Site from DM).		
Query 'Per DM CLR: Please update the condition to include the laterality of Knee Pain (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Dawn Killian (b) (4)	16 Sep 2020 19:26:22
' answered with 'cartidge build up added' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please update the condition to include the laterality of Knee Pain (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	15 Sep 2020 06:56:58
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
Data point term sent to Coder	System	18 Aug 2020 17:54:41
User entered 'knee pain'	Dawn Killian (b) (4)	18 Aug 2020 17:54:30
	(b) (4)	

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Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2007'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2007'	System	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2007'	System	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	19 Aug 2020 09:30:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 09:30:21
Data point term sent to Coder	System	18 Aug 2020 17:55:42
User entered 'vitamin d deficiency'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Un UNK 2019'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2019'	System	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2019'	System	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Cartilage therapeutic procedures, PT: Chondroplasty, LLT: Cartilage repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Sep 2020 07:20:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 07:20:44
Data point term sent to Coder	System	16 Sep 2020 19:19:19
User entered 'Bilateral cartilage buildup in knees'	Dawn Killian (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2007'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2009'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2007'	System	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2007'	System	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2009'	System	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2009'	System	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Spinal fracture, LLT: Spinal fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Sep 2020 06:19:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:19:59
Data point term sent to Coder	System	16 Sep 2020 19:22:26
User entered 'fractured back'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 1990'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 1990'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1990'	System	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1990'	System	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1990'	System	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1990'	System	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Penile and scrotal disorders (excl infections and inflammations), HLT: Penile disorders NEC (excl erection and ejaculation), PT: Peyronie's disease, LLT: Peyronie's disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Sep 2020 05:45:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 05:45:55
Data point term sent to Coder	System	16 Sep 2020 19:24:32
User entered 'peyronie's plaque'	Dawn Killian (b) (4)	16 Sep 2020 19:24:11
	(b) (4)	

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 1982'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 1988'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1982'	System	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1982'	System	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 1988'	System	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '1988'	System	16 Sep 2020 19:24:11

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	16 Sep 2020 19:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 19:28:41
Data point term sent to Coder	System	16 Sep 2020 19:27:38
User entered 'coronary artery disease'	Dawn Killian (b) (4)	16 Sep 2020 19:26:53
	(b) (4)	

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'UN UNK 2012'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4) Dawn Killian (b) (4)	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'Jan 2012'	System	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '2012'	System	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Drug delivery device implantation, LLT: Drug delivery device implantation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Mar 2021 19:29:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:29:30
Data point term sent to Coder	System	25 Mar 2021 19:29:20
User entered 'Insulin Pump'	Antonio Gutierrez (b) (4)	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'l'	(b) (4) Antonio Gutierrez (b) (4)	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	25 Mar 2021 19:29:13

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	10 Nov 2020 16:00:17
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 18:41:53
User entered '4 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 18:41:53
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per CDM: According to CRF, a time is required to go along with the date.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 14:50:29
Query 'Per CDM: According to CRF, a time is required to go along with the date.' answered with 'Updated' (Site from DM).		12 Aug 2020 12:21:15
User entered '14:37' reason for change: Data Entry Error		12 Aug 2020 12:20:59
User closed query 'Data is required. Please provide.' (Site from System).		11 Aug 2020 14:44:17
User opened query 'Per CDM: According to CRF, a time is required to go along with the date.' (Site from DM).		11 Aug 2020 14:44:16
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).		06 Aug 2020 18:40:51
User opened query 'Data is required. Please provide.' System		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '04 Aug 2020 14:37'	System	10 Nov 2020 16:00:17
User entered '4 Aug 2020 14:37'	System	12 Aug 2020 12:20:59
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '182.1' cm	(b) (4) (b) (4), (b) (6)	06 Aug 2020 18:40:03
DataPoint set to visible.	System	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '70.5' kg	(b) (4) (b) (4), (b) (6)	06 Aug 2020 18:40:03
DataPoint set to visible.	System	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
Amendment Manager: User entered '21.26029'	System	16 Sep 2020 23:43:05
User entered '21.3'	System	06 Aug 2020 18:40:03
DataPoint set to visible.	System	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'kg/m2'	System	06 Aug 2020 18:40:03
DataPoint set to visible.	System	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per CDM: Please remove the units 'beats/min, breaths/min,mmHg' recorded above ND - 'Not Done' from all the data fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:04:38
Query 'Per CDM: Please remove the units 'beats/min, breaths/min,mmHg' recorded above ND - 'Not Done' from all the data fields as appropriate. ' answered with 'these fields can't be removed' (Site from DM).	Dawn Killian (b) (4)	15 Sep 2020 21:47:47
User opened query 'Per CDM: Please remove the units 'beats/min, breaths/min,mmHg' recorded above ND - 'Not Done' from all the data fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:49:24
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).		17 Aug 2020 11:13:48
User entered missing code ND - Not Done; reason for change Data Entry Error		13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).		13 Aug 2020 15:17:03
User closed query 'Data is required. Please provide.' (Site from System).		11 Aug 2020 14:44:30
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).		11 Aug 2020 14:44:28
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).		06 Aug 2020 18:40:52
User opened query 'Data is required. Please provide.' System (Site from System).		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4)	17 Aug 2020 11:13:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 23:47:37
User entered 'Other (Other)' reason for change: Data Entry Error		13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).		13 Aug 2020 15:17:08
User closed query 'Data is required. Please provide.' (Site from System).		11 Aug 2020 14:44:36
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).		11 Aug 2020 14:44:34
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).		06 Aug 2020 18:41:02
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:37
User entered missing code ND - Not Done; reason for change Data Entry Error		13 Aug 2020 17:59:36
User entered empty.		06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	Katie McGuire (6275 - kmcguire21)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 17 Aug 2020 11:13:53
User entered missing code ND - Not Done; reason for change Data Entry Error		13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).		13 Aug 2020 15:17:13
User closed query 'Data is required. Please provide.' (Site from System).		11 Aug 2020 14:44:43
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).		11 Aug 2020 14:44:41
Query 'Data is required. Please provide.' answered with 'Combined visit' (Site from System).		06 Aug 2020 18:41:13
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'bpm'	System	13 Aug 2020 17:59:36
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4)	17 Aug 2020 11:13:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).		13 Aug 2020 15:17:18
User closed query 'Data is required. Please provide.' (Site from System).		11 Aug 2020 14:44:48
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).		11 Aug 2020 14:44:47
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).		06 Aug 2020 18:41:19
User opened query 'Data is required. Please provide.' System		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'breaths/min'	System	13 Aug 2020 17:59:36
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4)	17 Aug 2020 11:13:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).		13 Aug 2020 15:17:22
User closed query 'Data is required. Please provide.' (Site from System).		11 Aug 2020 14:44:53
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).		11 Aug 2020 14:44:52
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).		06 Aug 2020 18:41:26
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'mmHg'	System	13 Aug 2020 17:59:36
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4)	17 Aug 2020 11:14:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).		13 Aug 2020 15:17:27
User closed query 'Data is required. Please provide.' (Site from System).		11 Aug 2020 14:44:58
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).		11 Aug 2020 14:44:57
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).		06 Aug 2020 18:41:47
User opened query 'Data is required. Please provide.' System		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'mmHg'	System	13 Aug 2020 17:59:36
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07

US3292023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:21
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:42:07

US3292023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:00:34
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 08:48:07
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		01 Sep 2020 19:07:30
User entered '4 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 23:47:21
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:42:07

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 18:43:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'I'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:08:06

US3292023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 15:53:53
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:08:06

US3292023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[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 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Aug 2020 19:08:06

US3292023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'VISIT1'	System	06 Aug 2020 19:08:06

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 20:49:28

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:49

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:05:27
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:05:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 20:49:28
User entered '184711' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 20:49:28

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:49

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 20:49:28

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:49

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 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:49

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 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 12:25:34
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:49

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:49

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 12:25:53
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:01:20
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '14:37'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '04 Aug 2020 14:37'	System	10 Nov 2020 16:01:20
User entered '4 Aug 2020 14:37'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 13:26:51
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Victoria Hernandez (b) (4)	21 Sep 2020 20:19:11
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:43:05
User entered '35.7' C	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '68'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'bpm'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '14'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'breaths/min'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '126'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'mmHg'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '76'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'mmHg'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:01:20
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:36:08
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		06 Aug 2020 19:18:49
User entered '16:33'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '04 Aug 2020 16:33'	System	10 Nov 2020 16:01:20
User entered '4 Aug 2020 16:33'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '36.3' C	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '64'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'bpm'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '16'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'breaths/min'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '152'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'mmHg'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '76'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'mmHg'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:19:36

US3292023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:56
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:19:36

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: New Information	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Nov 2020 16:03:27
User entered '4 Aug 2020'	Nathan Cortez (b) (4)	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '16:00'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '04 Aug 2020 16:00'	System	10 Nov 2020 16:03:27
User entered '4 Aug 2020 16:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nathan Cortez (b) (4)	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'ONCE'	System	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 19:20:23

US3292023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: New Information	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Nov 2020 16:03:44
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:20:23

US3292023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '15:00'	(b) (4), (b) (6)	06 Aug 2020 19:20:23

US3292023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '04 Aug 2020 15:00'	System	10 Nov 2020 16:03:44
User entered '4 Aug 2020 15:00'	System	06 Aug 2020 19:20:23

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:26:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '04 Aug 2020' reason for change: New Information	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Nov 2020 16:03:57
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:21:04

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Aug 2020 19:21:04

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:21:04

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '15:25'	(b) (4), (b) (6)	06 Aug 2020 19:21:04

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered '04 Aug 2020 15:25'	System	10 Nov 2020 16:03:57
User entered '4 Aug 2020 15:25'	System	06 Aug 2020 19:21:04

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Aug 2020 19:21:21

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	13 Aug 2020 23:59:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:21:21

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty; reason for change Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	13 Aug 2020 23:59:45
User entered '15:25'	(b) (4)	
	(b) (4), (b) (6)	06 Aug 2020 19:21:21

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered empty.	System	13 Aug 2020 23:59:45
User entered '4 Aug 2020 15:25'	System	06 Aug 2020 19:21:21

US3292023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:21:37

US3292023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'I'	System	06 Aug 2020 19:21:37

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:38:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '605c89b0-845a-421c-8871-652c26295ac4' User entered 'Yes (Y)'	System	04 Aug 2020 21:39:53
	System	04 Aug 2020 21:39:53

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:38:32', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '605c89b0-845a-421c-8871-652c26295ac4' User entered '97.3'	System	04 Aug 2020 21:39:53
	System	04 Aug 2020 21:39:53

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:38:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '605c89b0-845a-421c-8871-652c26295ac4' User entered 'No (N)'	System	04 Aug 2020 21:39:53
	System	04 Aug 2020 21:39:53

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:39:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '605c89b0-845a-421c-8871-652c26295ac4' User entered '04 Aug 2020 16:39'	System	04 Aug 2020 21:39:53
	System	04 Aug 2020 21:39:53

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 16:20'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 18:50'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 19:45'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 2'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 3'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:02:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0dd1b7da-508c-4e5e-bf87-b0ce13106340' User entered 'Yes (Y)'	System	07 Aug 2020 14:02:39
	System	07 Aug 2020 14:02:39

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:01:42', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0dd1b7da-508c-4e5e-bf87-b0ce13106340' User entered '97.3'	System	07 Aug 2020 14:02:39
	System	07 Aug 2020 14:02:39

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:01:55', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0dd1b7da-508c-4e5e-bf87-b0ce13106340' User entered 'No (N)'	System	07 Aug 2020 14:02:39
	System	07 Aug 2020 14:02:39

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:02:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0dd1b7da-508c-4e5e-bf87-b0ce13106340' User entered '07 Aug 2020 09:02'	System	07 Aug 2020 14:02:39
	System	07 Aug 2020 14:02:39

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 4'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:11:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b81e789c-cba5-418a-adfe-e29d6b9bc431' User entered 'Yes (Y)'	System	08 Aug 2020 03:20:44
	System	08 Aug 2020 03:20:44

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:19:54', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b81e789c-cba5-418a-adfe-e29d6b9bc431' User entered '97.3'	System	08 Aug 2020 03:20:44
	System	08 Aug 2020 03:20:44

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:20:20', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b81e789c-cba5-418a-adfe-e29d6b9bc431'	System	08 Aug 2020 03:20:44
User entered 'No (N)'	System	08 Aug 2020 03:20:44

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:20:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b81e789c-cba5-418a-adfe-e29d6b9bc431' User entered '07 Aug 2020 22:20'	System	08 Aug 2020 03:20:44
	System	08 Aug 2020 03:20:44

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 5'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:42:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'bcff659b-396e-4ee8-ab9c-695b0998a285'	System	09 Aug 2020 02:43:26
User entered 'Yes (Y)'	System	09 Aug 2020 02:43:26

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:42:27', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'bcff659b-396e-4ee8-ab9c-695b0998a285' User entered '97.4'	System	09 Aug 2020 02:43:26
	System	09 Aug 2020 02:43:26

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:42:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'bcff659b-396e-4ee8-ab9c-695b0998a285'	System	09 Aug 2020 02:43:26
User entered 'No (N)'	System	09 Aug 2020 02:43:26

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:23', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'bcff659b-396e-4ee8-ab9c-695b0998a285'	System	09 Aug 2020 02:43:26
User entered '08 Aug 2020 21:43'	System	09 Aug 2020 02:43:26

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 6'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:44:45', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0283a759-b0e6-48af-8220-925c3b71b38b' User entered 'Yes (Y)'	System	10 Aug 2020 01:46:02
	System	10 Aug 2020 01:46:02

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:45:22', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0283a759-b0e6-48af-8220-925c3b71b38b' User entered '96.8'	System	10 Aug 2020 01:46:02
	System	10 Aug 2020 01:46:02

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:45:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0283a759-b0e6-48af-8220-925c3b71b38b' User entered 'No (N)'	System	10 Aug 2020 01:46:02
	System	10 Aug 2020 01:46:02

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:45:59', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0283a759-b0e6-48af-8220-925c3b71b38b' User entered '09 Aug 2020 20:45'	System	10 Aug 2020 01:46:02
	System	10 Aug 2020 01:46:02

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 7'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:40:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aa5eacfc-e433-4a60-a150-fd5fbb3b823a' User entered 'Yes (Y)'	System	11 Aug 2020 03:41:31
	System	11 Aug 2020 03:41:31

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:40:55', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aa5eacfc-e433-4a60-a150-fd5fbb3b823a' User entered '97.0'	System	11 Aug 2020 03:41:31
	System	11 Aug 2020 03:41:31

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:41:07', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aa5eacfc-e433-4a60-a150-fd5fbb3b823a' User entered 'No (N)'	System	11 Aug 2020 03:41:31
	System	11 Aug 2020 03:41:31

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:41:27', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aa5eacfc-e433-4a60-a150-fd5fbb3b823a' User entered '10 Aug 2020 22:41'	System	11 Aug 2020 03:41:31
	System	11 Aug 2020 03:41:31

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:40:20', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963'	System	04 Aug 2020 21:41:46
User entered 'None (1)'	System	04 Aug 2020 21:41:46

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:40:27', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963' User entered 'No (N)'	System	04 Aug 2020 21:41:46
	System	04 Aug 2020 21:41:46

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:40:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963' User entered 'No (N)'	System	04 Aug 2020 21:41:46
	System	04 Aug 2020 21:41:46

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:41:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963'	System	04 Aug 2020 21:41:46
User entered 'None (1)'	System	04 Aug 2020 21:41:46

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:41:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963' User entered '04 Aug 2020 16:41'	System	04 Aug 2020 21:41:46
	System	04 Aug 2020 21:41:46

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 16:20'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 18:50'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 19:45'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 2'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 3'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:04:11', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e'	System	07 Aug 2020 14:05:05
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 14:05:05

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:04:20', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e' User entered 'No (N)'	System	07 Aug 2020 14:05:05
	System	07 Aug 2020 14:05:05

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:04:26', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e' User entered 'No (N)'	System	07 Aug 2020 14:05:05
	System	07 Aug 2020 14:05:05

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:04:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e' User entered 'None (1)'	System	07 Aug 2020 14:05:05
	System	07 Aug 2020 14:05:05

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:04', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e' User entered '07 Aug 2020 09:05'	System	07 Aug 2020 14:05:05
	System	07 Aug 2020 14:05:05

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 4'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 5'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 6'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 7'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:41:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e' User entered 'None (1)'	System	11 Aug 2020 03:43:49
	System	11 Aug 2020 03:43:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:42:02', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e'	System	11 Aug 2020 03:43:49
User entered 'No (N)'	System	11 Aug 2020 03:43:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:42:11', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e' User entered 'No (N)'	System	11 Aug 2020 03:43:49
	System	11 Aug 2020 03:43:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:42:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e' User entered 'None (1)'	System	11 Aug 2020 03:43:49
	System	11 Aug 2020 03:43:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:43:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e' User entered '10 Aug 2020 22:43'	System	11 Aug 2020 03:43:49
	System	11 Aug 2020 03:43:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:13', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'None (0)'	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847' User entered 'None (0)'	System	04 Aug 2020 21:43:52
	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847' User entered 'None (0)'	System	04 Aug 2020 21:43:52
	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:38', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847' User entered 'None (0)'	System	04 Aug 2020 21:43:52
	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847' User entered 'None (0)'	System	04 Aug 2020 21:43:52
	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:43:01', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847' User entered 'None (0)'	System	04 Aug 2020 21:43:52
	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:43:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'No (N)'	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:43:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847' User entered '04 Aug 2020 16:43'	System	04 Aug 2020 21:43:52
	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 16:20'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 18:50'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Aug 2020 19:45'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 2'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 3'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b' User entered 'None (0)'	System	07 Aug 2020 14:06:34
	System	07 Aug 2020 14:06:34

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b' User entered 'None (0)'	System	07 Aug 2020 14:06:34
	System	07 Aug 2020 14:06:34

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b' User entered 'None (0)'	System	07 Aug 2020 14:06:34
	System	07 Aug 2020 14:06:34

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b' User entered 'None (0)'	System	07 Aug 2020 14:06:34
	System	07 Aug 2020 14:06:34

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:06:00', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b' User entered 'None (0)'	System	07 Aug 2020 14:06:34
	System	07 Aug 2020 14:06:34

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:06:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b' User entered 'None (0)'	System	07 Aug 2020 14:06:34
	System	07 Aug 2020 14:06:34

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:06:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b' User entered 'No (N)'	System	07 Aug 2020 14:06:34
	System	07 Aug 2020 14:06:34

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:06:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b' User entered '07 Aug 2020 09:06'	System	07 Aug 2020 14:06:34
	System	07 Aug 2020 14:06:34

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 4'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:20:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3' User entered 'None (0)'	System	08 Aug 2020 03:22:33
	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3' User entered 'None (0)'	System	08 Aug 2020 03:22:33
	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3' User entered 'None (0)'	System	08 Aug 2020 03:22:33
	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:20', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3' User entered 'None (0)'	System	08 Aug 2020 03:22:33
	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3' User entered 'None (0)'	System	08 Aug 2020 03:22:33
	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:29', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3' User entered 'None (0)'	System	08 Aug 2020 03:22:33
	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:42', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered 'No (N)'	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:22:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered '07 Aug 2020 22:22'	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 5'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923' User entered 'None (0)'	System	09 Aug 2020 02:45:42
	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923' User entered 'None (0)'	System	09 Aug 2020 02:45:42
	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:50', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923' User entered 'None (0)'	System	09 Aug 2020 02:45:42
	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923' User entered 'None (0)'	System	09 Aug 2020 02:45:42
	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:44:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923' User entered 'None (0)'	System	09 Aug 2020 02:45:42
	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:44:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923' User entered 'None (0)'	System	09 Aug 2020 02:45:42
	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:44:36', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered 'No (N)'	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:45:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923' User entered '08 Aug 2020 21:45'	System	09 Aug 2020 02:45:42
	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 6'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:46:32', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:46:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:46:50', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42' User entered 'None (0)'	System	10 Aug 2020 01:48:40
	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:46:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42' User entered 'None (0)'	System	10 Aug 2020 01:48:40
	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:47:07', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42' User entered 'None (0)'	System	10 Aug 2020 01:48:40
	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:47:12', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:47:21', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'No (N)'	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:48:34', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42' User entered '09 Aug 2020 20:48'	System	10 Aug 2020 01:48:40
	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 7'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	13 Aug 2020 16:15:30

US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '11 Aug 2020'	(b) (4) Dawn Killian (b) (4)	13 Aug 2020 16:15:30

US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dawn Killian (b) (4)	13 Aug 2020 16:15:30

US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	13 Aug 2020 16:15:30

US3292023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	13 Aug 2020 16:15:37

US3292023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'l'	System	13 Aug 2020 16:15:37

US3292023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	20 Aug 2020 00:16:58

US3292023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '18 Aug 2020'	(b) (4) Dawn Killian (b) (4)	20 Aug 2020 00:16:58

US3292023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dawn Killian (b) (4)	20 Aug 2020 00:16:58

US3292023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	20 Aug 2020 00:16:58

US3292023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	20 Aug 2020 00:16:47

US3292023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'l'	System	20 Aug 2020 00:16:47

US3292023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	26 Aug 2020 00:38:50

US3292023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '25 Aug 2020'	(b) (4) Kristy Trevino (b) (4)	26 Aug 2020 00:38:50

US3292023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	26 Aug 2020 00:38:50

US3292023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Kristy Trevino (b) (4)	26 Aug 2020 00:38:50

US3292023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	26 Aug 2020 00:38:55

US3292023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:16:07
User entered 'l'	System	26 Aug 2020 00:38:55

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:07:30

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '1 Sep 2020'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:07:30

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Clinic (Clinic)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:07:30

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'VISIT2'	System	01 Sep 2020 19:07:30

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User accepted default value 'Pre-Dose (PREDOSE)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '1 Sep 2020'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '11:55'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered '1 Sep 2020 11:55'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '36.2' C	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '70'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'bpm'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '12'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'breaths/min'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '132'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'mmHg'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '76'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'mmHg'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User accepted default value 'Post-Dose (POSTDOSE)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '1 Sep 2020'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '13:26'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered '1 Sep 2020 13:26'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '36.8' C	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '62'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'bpm'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '16'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'breaths/min'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '139'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'mmHg'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '74'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'mmHg'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:00

US3292023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '1 Sep 2020'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:00

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '1 Sep 2020'	(b) (4) Nathan Cortez (b) (4)	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '12:47'	(b) (4) Nathan Cortez (b) (4)	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered '1 Sep 2020 12:47'	System	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nathan Cortez (b) (4)	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'ONCE'	System	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:14

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '1 Sep 2020'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:14

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '12:17'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:14

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered '1 Sep 2020 12:17'	System	01 Sep 2020 19:09:14

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:26:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '01 Sep 2020'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '12:25'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered '01 Sep 2020 12:25'	System	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered empty.	System	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	01 Sep 2020 19:10:03

US3292023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'I'	System	01 Sep 2020 19:10:03

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:29:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '05a0d4d0-d688-4818-9872-254893835936' User entered 'Yes (Y)'	System	01 Sep 2020 18:30:41
	System	01 Sep 2020 18:30:41

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:30:07', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '05a0d4d0-d688-4818-9872-254893835936' User entered '98.3'	System	01 Sep 2020 18:30:41
	System	01 Sep 2020 18:30:41

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:30:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '05a0d4d0-d688-4818-9872-254893835936' User entered 'No (N)'	System	01 Sep 2020 18:30:41
	System	01 Sep 2020 18:30:41

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:30:38', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '05a0d4d0-d688-4818-9872-254893835936'	System	01 Sep 2020 18:30:41
User entered '01 Sep 2020 13:30'	System	01 Sep 2020 18:30:41

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T21:59:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ee88cf6d-58c6-4955-89fa-940df54263af' User entered 'Yes (Y)'	System	02 Sep 2020 03:01:10
	System	02 Sep 2020 03:01:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:00:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ee88cf6d-58c6-4955-89fa-940df54263af' User entered '98.1'	System	02 Sep 2020 03:01:10
	System	02 Sep 2020 03:01:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:00:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ee88cf6d-58c6-4955-89fa-940df54263af' User entered 'No (N)'	System	02 Sep 2020 03:01:10
	System	02 Sep 2020 03:01:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:00:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ee88cf6d-58c6-4955-89fa-940df54263af' User entered '01 Sep 2020 22:00'	System	02 Sep 2020 03:01:10
	System	02 Sep 2020 03:01:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 2'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T22:59:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aba0ead1-8b4d-4201-a104-913bc094c452'	System	03 Sep 2020 04:00:18
User entered 'Yes (Y)'	System	03 Sep 2020 04:00:18

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T22:59:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aba0ead1-8b4d-4201-a104-913bc094c452' User entered '99.3'	System	03 Sep 2020 04:00:18
	System	03 Sep 2020 04:00:18

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T22:59:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aba0ead1-8b4d-4201-a104-913bc094c452'	System	03 Sep 2020 04:00:18
User entered 'No (N)'	System	03 Sep 2020 04:00:18

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:00:13', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aba0ead1-8b4d-4201-a104-913bc094c452'	System	03 Sep 2020 04:00:18
User entered '02 Sep 2020 23:00'	System	03 Sep 2020 04:00:18

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 3'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:42:01', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5cb0eb66-b841-4c70-b485-aff973c8f0ca' User entered 'Yes (Y)'	System	04 Sep 2020 05:43:10
	System	04 Sep 2020 05:43:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:42:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5cb0eb66-b841-4c70-b485-aff973c8f0ca' User entered '98.2'	System	04 Sep 2020 05:43:10
	System	04 Sep 2020 05:43:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:42:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5cb0eb66-b841-4c70-b485-aff973c8f0ca' User entered 'No (N)'	System	04 Sep 2020 05:43:10
	System	04 Sep 2020 05:43:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:43:04', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5cb0eb66-b841-4c70-b485-aff973c8f0ca' User entered '04 Sep 2020 00:43'	System	04 Sep 2020 05:43:10
	System	04 Sep 2020 05:43:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 4'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:11:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7415cb8b-d74d-4381-8604-67af80ba3623' User entered 'Yes (Y)'	System	05 Sep 2020 04:12:50
	System	05 Sep 2020 04:12:50

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:12:22', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7415cb8b-d74d-4381-8604-67af80ba3623' User entered '97.6'	System	05 Sep 2020 04:12:50
	System	05 Sep 2020 04:12:50

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:12:33', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7415cb8b-d74d-4381-8604-67af80ba3623'	System	05 Sep 2020 04:12:50
User entered 'No (N)'	System	05 Sep 2020 04:12:50

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:12:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7415cb8b-d74d-4381-8604-67af80ba3623' User entered '04 Sep 2020 23:12'	System	05 Sep 2020 04:12:50
	System	05 Sep 2020 04:12:50

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 5'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:49:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'eae81253-fc6a-4f05-8b5b-808acf63ee72'	System	06 Sep 2020 04:50:15
User entered 'Yes (Y)'	System	06 Sep 2020 04:50:15

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:49:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'eae81253-fc6a-4f05-8b5b-808acf63ee72' User entered '97.2'	System	06 Sep 2020 04:50:15
	System	06 Sep 2020 04:50:15

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:49:53', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'eae81253-fc6a-4f05-8b5b-808acf63ee72'	System	06 Sep 2020 04:50:15
User entered 'No (N)'	System	06 Sep 2020 04:50:15

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:12', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'eae81253-fc6a-4f05-8b5b-808acf63ee72'	System	06 Sep 2020 04:50:15
User entered '05 Sep 2020 23:50'	System	06 Sep 2020 04:50:15

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 6'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:54:29', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3634a445-8d43-4965-a37f-b992bc91a9d2'	System	07 Sep 2020 02:55:25
User entered 'Yes (Y)'	System	07 Sep 2020 02:55:25

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3634a445-8d43-4965-a37f-b992bc91a9d2' User entered '96.6'	System	07 Sep 2020 02:55:25
	System	07 Sep 2020 02:55:25

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3634a445-8d43-4965-a37f-b992bc91a9d2'	System	07 Sep 2020 02:55:25
User entered 'No (N)'	System	07 Sep 2020 02:55:25

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:21', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3634a445-8d43-4965-a37f-b992bc91a9d2'	System	07 Sep 2020 02:55:25
User entered '06 Sep 2020 21:55'	System	07 Sep 2020 02:55:25

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 7'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:08:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a4c86b70-b1cd-4762-ba1a-1a6a0f0055ab' User entered 'Yes (Y)'	System	08 Sep 2020 03:09:20
	System	08 Sep 2020 03:09:20

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:08:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a4c86b70-b1cd-4762-ba1a-1a6a0f0055ab' User entered '97.6'	System	08 Sep 2020 03:09:20
	System	08 Sep 2020 03:09:20

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:00', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a4c86b70-b1cd-4762-ba1a-1a6a0f0055ab' User entered 'No (N)'	System	08 Sep 2020 03:09:20
	System	08 Sep 2020 03:09:20

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a4c86b70-b1cd-4762-ba1a-1a6a0f0055ab' User entered '07 Sep 2020 22:09'	System	08 Sep 2020 03:09:20
	System	08 Sep 2020 03:09:20

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:30:53', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e' User entered 'None (1)'	System	01 Sep 2020 18:31:30
	System	01 Sep 2020 18:31:30

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e' User entered 'No (N)'	System	01 Sep 2020 18:31:30
	System	01 Sep 2020 18:31:30

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:10', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e' User entered 'No (N)'	System	01 Sep 2020 18:31:30
	System	01 Sep 2020 18:31:30

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e' User entered 'None (1)'	System	01 Sep 2020 18:31:30
	System	01 Sep 2020 18:31:30

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e' User entered '01 Sep 2020 13:31'	System	01 Sep 2020 18:31:30
	System	01 Sep 2020 18:31:30

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:01:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd'	System	02 Sep 2020 03:03:08
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 03:03:08

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:02:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd' User entered 'No (N)'	System	02 Sep 2020 03:03:08
	System	02 Sep 2020 03:03:08

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:02:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd' User entered 'No (N)'	System	02 Sep 2020 03:03:08
	System	02 Sep 2020 03:03:08

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:02:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd' User entered 'None (1)'	System	02 Sep 2020 03:03:08
	System	02 Sep 2020 03:03:08

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd' User entered '01 Sep 2020 22:03'	System	02 Sep 2020 03:03:08
	System	02 Sep 2020 03:03:08

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 2'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:00:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3'	System	03 Sep 2020 04:02:07
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 04:02:07

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:01:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3' User entered 'No (N)'	System	03 Sep 2020 04:02:07
	System	03 Sep 2020 04:02:07

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:01:15', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3'	System	03 Sep 2020 04:02:07
User entered 'No (N)'	System	03 Sep 2020 04:02:07

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:01:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3'	System	03 Sep 2020 04:02:07
User entered 'None (1)'	System	03 Sep 2020 04:02:07

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:02:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3' User entered '02 Sep 2020 23:02'	System	03 Sep 2020 04:02:07
	System	03 Sep 2020 04:02:07

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 3'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:43:32', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3'	System	04 Sep 2020 05:45:29
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 05:45:29

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:43:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3' User entered 'No (N)'	System	04 Sep 2020 05:45:29
	System	04 Sep 2020 05:45:29

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3' User entered 'No (N)'	System	04 Sep 2020 05:45:29
	System	04 Sep 2020 05:45:29

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:44:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3' User entered 'None (1)'	System	04 Sep 2020 05:45:29
	System	04 Sep 2020 05:45:29

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3' User entered '04 Sep 2020 00:45'	System	04 Sep 2020 05:45:29
	System	04 Sep 2020 05:45:29

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 4'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:13:22', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11'	System	05 Sep 2020 04:14:23
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 04:14:23

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:13:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11' User entered 'No (N)'	System	05 Sep 2020 04:14:23
	System	05 Sep 2020 04:14:23

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:13:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11' User entered 'No (N)'	System	05 Sep 2020 04:14:23
	System	05 Sep 2020 04:14:23

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:13:45', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11' User entered 'None (1)'	System	05 Sep 2020 04:14:23
	System	05 Sep 2020 04:14:23

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:14:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11' User entered '04 Sep 2020 23:14'	System	05 Sep 2020 04:14:23
	System	05 Sep 2020 04:14:23

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 5'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b' User entered 'None (1)'	System	06 Sep 2020 04:51:10
	System	06 Sep 2020 04:51:10

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b' User entered 'No (N)'	System	06 Sep 2020 04:51:10
	System	06 Sep 2020 04:51:10

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b' User entered 'No (N)'	System	06 Sep 2020 04:51:10
	System	06 Sep 2020 04:51:10

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b' User entered 'None (1)'	System	06 Sep 2020 04:51:10
	System	06 Sep 2020 04:51:10

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:08', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b' User entered '05 Sep 2020 23:51'	System	06 Sep 2020 04:51:10
	System	06 Sep 2020 04:51:10

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 6'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:45', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a' User entered 'None (1)'	System	07 Sep 2020 02:56:32
	System	07 Sep 2020 02:56:32

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a' User entered 'No (N)'	System	07 Sep 2020 02:56:32
	System	07 Sep 2020 02:56:32

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a' User entered 'No (N)'	System	07 Sep 2020 02:56:32
	System	07 Sep 2020 02:56:32

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a' User entered 'None (1)'	System	07 Sep 2020 02:56:32
	System	07 Sep 2020 02:56:32

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:29', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a' User entered '06 Sep 2020 21:56'	System	07 Sep 2020 02:56:32
	System	07 Sep 2020 02:56:32

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 7'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd' User entered 'None (1)'	System	08 Sep 2020 03:10:04
	System	08 Sep 2020 03:10:04

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd' User entered 'No (N)'	System	08 Sep 2020 03:10:04
	System	08 Sep 2020 03:10:04

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd' User entered 'No (N)'	System	08 Sep 2020 03:10:04
	System	08 Sep 2020 03:10:04

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd' User entered 'None (1)'	System	08 Sep 2020 03:10:04
	System	08 Sep 2020 03:10:04

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:01', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd' User entered '07 Sep 2020 22:10'	System	08 Sep 2020 03:10:04
	System	08 Sep 2020 03:10:04

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered 'None (0)'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered 'None (0)'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered 'None (0)'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:55', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered 'None (0)'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered 'None (0)'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:32:02', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered 'None (0)'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:32:13', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered 'No (N)'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:32:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered '01 Sep 2020 13:32'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:26', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9' User entered 'None (0)'	System	02 Sep 2020 03:05:16
	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:33', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9' User entered 'None (0)'	System	02 Sep 2020 03:05:16
	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9' User entered 'None (0)'	System	02 Sep 2020 03:05:16
	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9' User entered 'None (0)'	System	02 Sep 2020 03:05:16
	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:04:01', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9' User entered 'None (0)'	System	02 Sep 2020 03:05:16
	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:04:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9' User entered 'None (0)'	System	02 Sep 2020 03:05:16
	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:04:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered 'No (N)'	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:05:11', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9' User entered '01 Sep 2020 22:05'	System	02 Sep 2020 03:05:16
	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 2'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:03:51', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ca9d-4273-89a4-d2b4ab54e277' User entered 'None (0)'	System	03 Sep 2020 04:05:51
	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:10', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ca9d-4273-89a4-d2b4ab54e277' User entered 'None (0)'	System	03 Sep 2020 04:05:51
	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ca9d-4273-89a4-d2b4ab54e277' User entered 'None (0)'	System	03 Sep 2020 04:05:51
	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ca9d-4273-89a4-d2b4ab54e277' User entered 'None (0)'	System	03 Sep 2020 04:05:51
	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ca9d-4273-89a4-d2b4ab54e277' User entered 'None (0)'	System	03 Sep 2020 04:05:51
	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ca9d-4273-89a4-d2b4ab54e277' User entered 'None (0)'	System	03 Sep 2020 04:05:51
	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:05:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ca9d-4273-89a4-d2b4ab54e277' User entered 'No (N)'	System	03 Sep 2020 04:05:51
	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:05:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ca9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered '02 Sep 2020 23:05'	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 3'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d' User entered 'None (0)'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:53', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d' User entered 'None (0)'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d' User entered 'None (0)'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d' User entered 'None (0)'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d' User entered 'None (0)'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:21', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d' User entered 'None (0)'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d' User entered 'No (N)'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:51', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d' User entered '04 Sep 2020 00:46'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 4'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:14:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79' User entered 'None (0)'	System	05 Sep 2020 04:16:30
	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:14:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79' User entered 'None (0)'	System	05 Sep 2020 04:16:30
	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:14:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79' User entered 'None (0)'	System	05 Sep 2020 04:16:30
	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:15:07', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79' User entered 'None (0)'	System	05 Sep 2020 04:16:30
	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:15:13', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79' User entered 'None (0)'	System	05 Sep 2020 04:16:30
	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:15:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79' User entered 'None (0)'	System	05 Sep 2020 04:16:30
	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:15:42', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79' User entered 'No (N)'	System	05 Sep 2020 04:16:30
	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:16:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered '04 Sep 2020 23:16'	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 5'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa' User entered 'None (0)'	System	06 Sep 2020 04:53:01
	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:34', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa' User entered 'None (0)'	System	06 Sep 2020 04:53:01
	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa' User entered 'None (0)'	System	06 Sep 2020 04:53:01
	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa' User entered 'None (0)'	System	06 Sep 2020 04:53:01
	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:52:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:52:14', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa' User entered 'None (0)'	System	06 Sep 2020 04:53:01
	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:52:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa' User entered 'No (N)'	System	06 Sep 2020 04:53:01
	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:52:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa' User entered '05 Sep 2020 23:52'	System	06 Sep 2020 04:53:01
	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 6'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:45', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b' User entered 'None (0)'	System	07 Sep 2020 02:58:03
	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b' User entered 'None (0)'	System	07 Sep 2020 02:58:03
	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b' User entered 'None (0)'	System	07 Sep 2020 02:58:03
	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b' User entered 'None (0)'	System	07 Sep 2020 02:58:03
	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:11', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b' User entered 'None (0)'	System	07 Sep 2020 02:58:03
	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:15', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b' User entered 'None (0)'	System	07 Sep 2020 02:58:03
	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b' User entered 'No (N)'	System	07 Sep 2020 02:58:03
	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:59', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b' User entered '06 Sep 2020 21:57'	System	07 Sep 2020 02:58:03
	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 7'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:14', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11' User entered 'None (0)'	System	08 Sep 2020 03:11:08
	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:21', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11' User entered 'None (0)'	System	08 Sep 2020 03:11:08
	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11' User entered 'None (0)'	System	08 Sep 2020 03:11:08
	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11' User entered 'None (0)'	System	08 Sep 2020 03:11:08
	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:34', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11' User entered 'None (0)'	System	08 Sep 2020 03:11:08
	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11' User entered 'None (0)'	System	08 Sep 2020 03:11:08
	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11' User entered 'No (N)'	System	08 Sep 2020 03:11:08
	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:11:02', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11' User entered '07 Sep 2020 22:11'	System	08 Sep 2020 03:11:08
	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:26:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	11 Sep 2020 14:23:11

US3292023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '11 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	11 Sep 2020 14:23:11

US3292023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	11 Sep 2020 14:23:11

US3292023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	11 Sep 2020 14:23:11

US3292023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	11 Sep 2020 14:23:18

US3292023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'l'	System	11 Sep 2020 14:23:18

US3292023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 15:05:25

US3292023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '17 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 15:05:25

US3292023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 15:05:25

US3292023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 15:05:25

US3292023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 15:05:33

US3292023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'l'	System	17 Sep 2020 15:05:33

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 14:04:43

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '24 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 14:04:43

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 14:04:43

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 14:04:43

US3292023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 14:04:47

US3292023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'l'	System	24 Sep 2020 14:04:47

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:39:28

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '29 Sep 2020'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:39:28

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Clinic (Clinic)'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:39:28

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'VISIT3'	System	29 Sep 2020 20:39:28

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '29 Sep 2020'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '13:59'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered '29 Sep 2020 13:59'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '36.5' C	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '80'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'bpm'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '16'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'breaths/min'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '111'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'mmHg'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '72'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'mmHg'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15

US3292023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'No (N)'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:39

US3292023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:39

US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:55

US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '29 Sep 2020'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:55

US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '14:29'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:40:55

US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered '29 Sep 2020 14:29'	System	29 Sep 2020 20:40:55

US3292023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	29 Sep 2020 20:41:00

US3292023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'I'	System	29 Sep 2020 20:41:00

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 64'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-06T14:41:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'fla7c21a-337f-4d8d-a9e2-40cb96980080' User entered 'No (N)'	System	06 Oct 2020 19:42:48
	System	06 Oct 2020 19:42:48

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-06T14:42:00', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'fla7c21a-337f-4d8d-a9e2-40cb96980080' User entered 'No (N)'	System	06 Oct 2020 19:42:48
	System	06 Oct 2020 19:42:48

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-06T14:42:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'fla7c21a-337f-4d8d-a9e2-40cb96980080' User entered '06 Oct 2020 14:42:44'	System	06 Oct 2020 19:42:48
	System	06 Oct 2020 19:42:48

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 71'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-14T11:30:00', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '09f06ca3-ce95-4da3-9ef2-ef5b1ce32187'	System	14 Oct 2020 16:30:42
User entered 'No (N)'	System	14 Oct 2020 16:30:42

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-14T11:30:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '09f06ca3-ce95-4da3-9ef2-ef5b1ce32187'	System	14 Oct 2020 16:30:42
User entered 'No (N)'	System	14 Oct 2020 16:30:42

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-14T11:30:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '09f06ca3-ce95-4da3-9ef2-ef5b1ce32187' User entered '14 Oct 2020 11:30:39'	System	14 Oct 2020 16:30:42
	System	14 Oct 2020 16:30:42

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 78'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-20T13:58:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25f6bc3d-7efa-48c7-99f4-32e734d8ab6d'	System	20 Oct 2020 19:30:57
User entered 'No (N)'	System	20 Oct 2020 19:30:57

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-20T14:00:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25f6bc3d-7efa-48c7-99f4-32e734d8ab6d'	System	20 Oct 2020 19:30:57
User entered 'No (N)'	System	20 Oct 2020 19:30:57

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-20T14:30:50', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25f6bc3d-7efa-48c7-99f4-32e734d8ab6d' User entered '20 Oct 2020 14:30:50'	System	20 Oct 2020 19:30:57
	System	20 Oct 2020 19:30:57

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 92'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-04T16:04:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2daed050-a4f6-4dd4-b5d6-fa51021d8858' User entered 'No (N)'	System	04 Nov 2020 22:05:07
	System	04 Nov 2020 22:05:07

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-04T16:04:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2daed050-a4f6-4dd4-b5d6-fa51021d8858'	System	04 Nov 2020 22:05:07
User entered 'No (N)'	System	04 Nov 2020 22:05:07

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-04T16:05:04', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2daed050-a4f6-4dd4-b5d6-fa51021d8858' User entered '04 Nov 2020 16:05:04'	System	04 Nov 2020 22:05:07
	System	04 Nov 2020 22:05:07

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 99'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-11T05:18:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5bcf6e77-4505-4e32-8336-cf236af3e29b' User entered 'No (N)'	System	11 Nov 2020 11:18:41
	System	11 Nov 2020 11:18:41

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-11T05:18:15', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5bcf6e77-4505-4e32-8336-cf236af3e29b'	System	11 Nov 2020 11:18:41
User entered 'No (N)'	System	11 Nov 2020 11:18:41

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-11T05:18:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5bcf6e77-4505-4e32-8336-ef236af3e29b' User entered '11 Nov 2020 05:18:39'	System	11 Nov 2020 11:18:41
	System	11 Nov 2020 11:18:41

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 106'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-17T17:49:22', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '575a067a-d165-492e-ba08-d420abb69968' User entered 'No (N)'	System	17 Nov 2020 23:50:18
	System	17 Nov 2020 23:50:18

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-17T17:49:55', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '575a067a-d165-492e-ba08-d420abb69968'	System	17 Nov 2020 23:50:18
User entered 'No (N)'	System	17 Nov 2020 23:50:18

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-17T17:50:15', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '575a067a-d165-492e-ba08-d420abb69968' User entered '17 Nov 2020 17:50:15'	System	17 Nov 2020 23:50:18
	System	17 Nov 2020 23:50:18

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	
Data entry locked.	System	19 Nov 2020 12:52:45
User entered 'Day 113'	System	04 Aug 2020 21:09:49
	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-24T10:47:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '94d45ed6-ccda-49cc-a8af-e71ef2dd2fda'	System	24 Nov 2020 16:47:43
User entered 'No (N)'	System	24 Nov 2020 16:47:43
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	
	System	19 Nov 2020 12:52:45

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-24T10:47:17', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '94d45ed6-ccda-49cc-a8af-e71ef2dd2fda'	System	24 Nov 2020 16:47:43
User entered 'No (N)'	System	24 Nov 2020 16:47:43
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	
	System	19 Nov 2020 12:52:45

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-24T10:47:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '94d45ed6-ccda-49cc-a8af-e71ef2dd2fda' User entered '24 Nov 2020 10:47:39'	System	24 Nov 2020 16:47:43
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	19 Nov 2020 12:52:45

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	
Data entry locked.	System	19 Nov 2020 12:52:45
User entered '22 Nov 2020 00:01'	System	04 Aug 2020 21:09:49
	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:43:57
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	
Data entry locked.	System	19 Nov 2020 12:52:45
User entered '26 Nov 2020 23:59'	System	04 Aug 2020 21:09:49
	System	04 Aug 2020 21:09:49

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-12-06T07:54:24', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25e4ef1d-4255-4286-87bb-905f896e5771'	System	06 Dec 2020 13:56:55
User entered 'Yes (Y)'	System	06 Dec 2020 13:56:55

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-12-06T07:54:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25e4ef1d-4255-4286-87bb-905f896e5771'	System	06 Dec 2020 13:56:55
User entered 'No (N)'	System	06 Dec 2020 13:56:55

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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)	02 May 2021 13:52:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-12-06T07:55:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25e4ef1d-4255-4286-87bb-905f896e5771'	System	06 Dec 2020 13:56:55
User entered 'No (N)'	System	06 Dec 2020 13:56:55

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-12-06T07:56:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25e4ef1d-4255-4286-87bb-905f896e5771'	System	06 Dec 2020 13:56:55
User entered 'No (N)'	System	06 Dec 2020 13:56:55

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-12-06T07:56:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25e4ef1d-4255-4286-87bb-905f896e5771' User entered '06 Dec 2020 07:56:52'	System	06 Dec 2020 13:56:55
	System	06 Dec 2020 13:56:55

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Have you been exposed to someone with 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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[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)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:52:45

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	27 Oct 2020 19:47:54

US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '27 Oct 2020'	(b) (4) Nathan Cortez (b) (4)	27 Oct 2020 19:47:54

US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nathan Cortez (b) (4)	27 Oct 2020 19:47:54

US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	27 Oct 2020 19:47:54

US3292023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	27 Oct 2020 19:48:00

US3292023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:17:15
User entered 'l'	System	27 Oct 2020 19:48:00

US3292023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	02 Dec 2020 17:24:20

US3292023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered '30 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	02 Dec 2020 17:24:20

US3292023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	02 Dec 2020 17:24:20

US3292023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:24:20

US3292023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	02 Dec 2020 17:24:24

US3292023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User entered 'I'	System	02 Dec 2020 17:24:24

US3292023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	27 Jan 2021 18:27:06

US3292023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered '30 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	27 Jan 2021 18:27:06

US3292023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Gerardo Pena (b) (4)	27 Jan 2021 18:27:06

US3292023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'three attempts made to contact subject; no answer.'	(b) (4) Gerardo Pena (b) (4)	27 Jan 2021 18:27:06

US3292023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	27 Jan 2021 18:27:09

US3292023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:06:42
User entered 'l'	System	27 Jan 2021 18:27:09

US3292023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:09:18
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:31:10

US3292023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:09:18
User entered empty.	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:31:10

US3292023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:09:18
User entered empty.	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:31:10

US3292023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:09:18
User entered 'subject has died.'	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:31:10

US3292023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:09:18
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:31:17

US3292023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	25 Feb 2021 22:31:17

US3292023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:26:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:33
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:36:24

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:31
User entered 'USA-US072-2020-mRNA-1273-P301000007'	System	28 Oct 2020 17:21:27
User entered 'New'	(b) (4), (b) (6)	28 Oct 2020 17:21:27

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
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)	27 Oct 2020 18:59:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 18:59:27
Data point term sent to Coder	System	27 Oct 2020 18:58:58
User entered 'Diabetic ketoacidosis'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered empty.	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '26 Oct 2020'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered empty.	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'l'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '26 Oct 2020'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered empty.	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'l'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered empty.	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:53:32
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		25 Mar 2021 14:53:29
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'info not available ' (Site from Safety).	Victoria Hernandez (b) (4)	24 Mar 2021 17:19:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'info not available ' (Site from Safety).	Victoria Hernandez (b) (4)	24 Mar 2021 17:19:10
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 19:32:34
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		16 Nov 2020 19:32:09

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any available details on the subject's malfunctioning insulin pump. Was a co-suspect medication implicated in the reported event?' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:27:45
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 Nov 2020 16:27:43
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		09 Nov 2020 16:27:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		09 Nov 2020 16:27:39
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Will be provided once medical records become available' (Site from Safety).	Darlington Akahara (b) (4)	08 Nov 2020 22:26:14
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Will be provided once medical records become available' (Site from Safety).	Darlington Akahara (b) (4)	08 Nov 2020 22:25:57
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 testing not done, as per patient. Will note in progress note.' (Site from Safety).	Antonio Gutierrez (b) (4)	06 Nov 2020 19:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any available details on the subject's malfunctioning insulin pump. Was a co-suspect medication implicated in the reported event?' answered with 'As of conversation with patient on 06NOV2020, pt states that scar tissue in patient's skin was preventing the flow of insulin. This conversation will be noted in progress note.' (Site from Safety).	Antonio Gutierrez (b) (4)	06 Nov 2020 19:41:32
User opened query 'PV Query: Please provide any available details on the subject's malfunctioning insulin pump. Was a co-suspect medication implicated in the reported event?' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:12:43
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).		05 Nov 2020 23:12:23
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		05 Nov 2020 23:12:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		05 Nov 2020 23:11:48
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient contacted staff today, 27OCT2020, to state that he had been hospitalized recently due to Diabetic Ketoacidosis. On Thursday, 22OCT2020, patient states that he was not feeling well due to an insulin pump that was not functioning correctly. He states that he had been waiting for a replacement that was overdue for delivery. Patient states that he had checked his blood sugar, which had been registering between 500 and 700. The lowest reading registered at 468. After realizing that his levels would not drop to normal levels, he contacted EMS and was transported to a local hospital. Upon being evaluated by ER physicians, the patient was started on an insulin drip. The patient was not able to remember any other medications that he may have been given. Patient was discharged in stable condition on 26OCT2020. Medical records will be requested as soon as possible. No further information available at this time.'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '0'	System	27 Oct 2020 18:58:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Dec 2020 17:29:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 17:29:51
Data point term sent to Coder	System	02 Dec 2020 17:28:34
User entered 'tooth infection'	Gerardo Pena (b) (4)	02 Dec 2020 17:28:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

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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)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '27 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
User entered empty.	System	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '30 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4)	
	Gerardo Pena (b) (4)	02 Dec 2020 17:28:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
User entered empty.	System	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 21:04:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	11 Jan 2021 21:04:22
User opened query 'Data is required. Please complete.' (Site from System).	Victoria Hernandez (b) (4)	11 Jan 2021 21:04:22
User entered empty.	(b) (4)	
	System	02 Dec 2020 17:28:10
	Gerardo Pena (b) (4)	02 Dec 2020 17:28:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	11 Jan 2021 21:04:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 21:04:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	11 Jan 2021 21:04:22
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:28:10
User entered empty.	Gerardo Pena (b) (4)	02 Dec 2020 17:28:10
	(b) (4)	

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the corresponding treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:49:55
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the corresponding treatment procedure as appropriate. Otherwise, clarify.'	Dawn Killian (b) (4)	24 Mar 2021 19:58:47
answered with 'updated procedures' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the corresponding treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:10:49
User entered 'l'	Gerardo Pena (b) (4)	02 Dec 2020 17:28:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	02 Dec 2020 17:28:10

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
User entered '0'	System	02 Dec 2020 17:28:10

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44
User entered 'I'	System	02 Dec 2020 17:28:10

US3292023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:44

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:08:55
User entered 'USA-US072-2021-mRNA-1273-P301000014'	System	22 Feb 2021 20:08:49
User entered 'New'	(b) (4), (b) (6)	22 Feb 2021 20:08:49

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 21:24:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 21:24:56
Data point term sent to Coder	System	09 Mar 2021 22:52:00
Coding entries removed.	Antonio Gutierrez (b) (4)	09 Mar 2021 22:51:09
User entered 'End stage congestive heart failure' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	09 Mar 2021 22:51:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Death - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 17:09:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 17:09:01
Data point term sent to Coder	System	22 Feb 2021 17:07:57
User entered 'Death'	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 13:58:51
User entered '19 Dec 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Mar 2021 23:07:21
User entered '24 Jan 2021'	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 13:58:51
User entered '23 Jan 2021' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	09 Mar 2021 23:07:21
User entered '24 Jan 2021'	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Grade 4 (Grade 4)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'I'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 14:24:26
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Emailed to address above on 29MAR2021 @ 10:39am central.' (Site from Safety).	Antonio Gutierrez (b) (4)	29 Mar 2021 15:40:36
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 20:50:40
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		09 Mar 2021 23:05:06
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		09 Mar 2021 23:05:06
User entered 'I' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	09 Mar 2021 23:05:06

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	09 Mar 2021 22:51:09
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 10:00:39
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'No hospitalization data provided. ' (Site from System).	Antonio Gutierrez (b) (4)	22 Feb 2021 17:08:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Feb 2021 17:07:26
User entered '0'	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 13:58:51
User entered '19 Dec 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Mar 2021 23:05:06
User entered empty.	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 13:58:51
User entered '20 Jan 2021' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Mar 2021 23:05:06
User entered empty.	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

US3292023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	09 Mar 2021 22:51:09
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		09 Mar 2021 22:51:09
User entered 'Yes (Y)' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Mar 2021 22:51:09
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	22 Feb 2021 17:07:26
User entered 'Unknown (UNK)'	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:45:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:51:25
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	16 Apr 2021 15:48:53
Signature has been broken.	Antonio Gutierrez (b) (4)	16 Apr 2021 15:48:53
User entered '32' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	16 Apr 2021 15:48:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 08:49:52
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'number of days is unknown. medical records do not specify' (Site from System).	Antonio Gutierrez (b) (4)	09 Mar 2021 23:05:38
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	09 Mar 2021 23:05:06
User entered empty.	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:38:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:37:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0' reason for change: Per Query Resolution	(b) (4)	
	Antonio Gutierrez (b) (4)	29 Mar 2021 16:00:52
User entered '1'	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:37:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Antonio Gutierrez (b) (4)	29 Mar 2021 16:00:52
User entered '0'	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:37:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:37:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered 'Fatal (FATAL)'	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:37:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:37:20
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 13:58:51
User closed query 'PV Query: please clarify if diabetic ketoacidosis, lactic acidosis, hyperkalemia, acute kidney injury, sepsis, femur fracture, acute hypoxemic respiratory failure, cardiogenic shock, STEMI, dilated cardiomyopathy meet criteria for SAE reporting ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 15:20:58
Query 'PV Query: please clarify if diabetic ketoacidosis, lactic acidosis, hyperkalemia, acute kidney injury, sepsis, femur fracture, acute hypoxemic respiratory failure, cardiogenic shock, STEMI, dilated cardiomyopathy meet criteria for SAE reporting ' answered with 'no correct as is' (Site from Safety).	Dawn Killian (b) (4)	12 Apr 2021 18:09:15
User closed query 'Pe DM CLR: Narrative indicates that the subject was given IV ABX/ANTIVIRALS. However, there are no recorded ConMeds that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:05:09
Query 'Pe DM CLR: Narrative indicates that the subject was given IV ABX/ANTIVIRALS. However, there are no recorded ConMeds that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' answered with 'conmed log updated' (Site from DM).	Antonio Gutierrez (b) (4)	29 Mar 2021 16:00:19
User closed query 'PV Query: Please confirm if subject's use of an insulin pump is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 16:03:06
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' (Site from Safety).		26 Mar 2021 16:02:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Narrative](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	26 Mar 2021 16:02:40
Query 'PV Query: Please confirm if subject's use of an insulin pump is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. ' answered with 'added to MH' (Site from Safety).	Antonio Gutierrez (b) (4)	25 Mar 2021 19:30:12
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' answered with 'As per medical records, "His wife reported patient has been having a lot of fluctuations on his glucose levels over the last few days and he became confused when glucose abnormal and he lost his balance and fell."' (Site from Safety).	Antonio Gutierrez (b) (4)	25 Mar 2021 19:21:12
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 'As per medical records, COVID-19 PCR test completed with result "Not Detected"' (Site from Safety).	Antonio Gutierrez (b) (4)	25 Mar 2021 19:17:03
User opened query 'Pe DM CLR: Narrative indicates that the subject was given IV ABX/ANTIVIRALS. However, there are no recorded ConMeds that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:43:49
User opened query 'PV Query: please clarify if diabetic ketoacidosis, lactic acidosis, hyperkalemia, acute kidney injury, sepsis, femur fracture, acute hypoxemic respiratory failure, cardiogenic shock, STEMI, dilated cardiomyopathy meet criteria for SAE reporting ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 20:51:04
User opened query 'PV Query: Please confirm if subject's use of an insulin pump is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 20:50:56

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 20:50:22
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).	(b) (4), (b) (6)	16 Mar 2021 20:50:14
User closed query 'PV Query: Please request for the cause of death/ autopsy report if available. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:46:34
User closed query 'PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' (Site from Safety).		10 Mar 2021 14:46:28
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so ' (Site from Safety).		10 Mar 2021 14:46:24
User closed query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so. ' (Site from Safety).		10 Mar 2021 14:46:21
Query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so. ' answered with 'No autopsy performed ' (Site from Safety).	Antonio Gutierrez (b) (4)	09 Mar 2021 23:06:37
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so ' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	09 Mar 2021 23:06:23

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' answered with 'Cause: end stage heart failure' (Site from Safety).	Antonio Gutierrez (b) (4)	09 Mar 2021 23:06:15
Query 'PV Query: Please request for the cause of death/ autopsy report if available. ' answered with 'COD: End stage heart failure' (Site from Safety).	Antonio Gutierrez (b) (4)	09 Mar 2021 23:06:03
User entered '80 year old man with Type 1 diabetes on insulin pump initially admitted on 12/19/2020 with DKA, lactic acidosis, hyperkalemia, AKI, severe sepsis criteria as well as femur fracture after fall prior to this admission. On 12/20, he then developed acute hypoxemic respiratory failure and cardiogenic shock due to STEMI and found to have severely depressed EF of 20% due to acute systolic chf/dilated cardiomyopathy. No improvement in mentation and failed swallow study due persistent AMS, also with persistent leukocytosis w/o clear source despite aggressive IV abx/antivirals. Overall hospital course discussed with son to include no improvement in patient's mental status. Hospice discussed. Consent for hospice signed on 1/19/2021. Transferred to hospice 1/20/2021 with terminal End stage congestive heart failure. Patient passed on 23JAN2021.' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Mar 2021 23:05:06
User opened query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:14:29
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so ' (Site from Safety).		02 Mar 2021 15:14:17
User opened query 'PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' (Site from Safety).		02 Mar 2021 15:14:09

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please request for the cause of death/ autopsy report if available. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:14:01
User entered 'Site staff have been trying to contact this patient since December 6, 2020 after patient stopped completing eDiaries and Safety phone calls. All phone numbers and emails in patient's chart and medical record were utilized with no success. Prior to finalizing patient's LTFU status, one more attempt to contact patient's wife was made today, 22Feb2021. Wife answered and stated her husband passed on 24JAN2021. She was emotional and unable to provide further information at this time. We will follow up and attempt to collect as much information as possible as soon as possible.'	Antonio Gutierrez (b) (4)	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	22 Feb 2021 17:07:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '1'	System	09 Mar 2021 22:51:09
User entered '0'	System	22 Feb 2021 17:07:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per ETRTR: Please add ConMeds provided for SAE "Diabetic Ketoacidosis ", thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 18:05:45
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:26
Query 'Per ETRTR: Please add ConMeds provided for SAE "Diabetic Ketoacidosis ", thanks.' answered with 'ConMeds updated ' (Site from CRA).	Antonio Gutierrez (b) (4)	04 Nov 2020 00:08:00
User opened query 'Per ETRTR: Please add ConMeds provided for SAE "Diabetic Ketoacidosis ", thanks.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:02:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 11:54:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 11:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 11:59:20
Data point term sent to Coder	System	07 Aug 2020 11:58:34
User entered 'Vitamin B12'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:56:33
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:26:56
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:26:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:26:49
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:30:54
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Preventative'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '50'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mcg'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:01:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 11:57:40
User entered 'un UNK 2016'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 12:01:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 12:01:05
Data point term sent to Coder	System	07 Aug 2020 12:00:34
User entered 'Vitamin C'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per CDM: Response noted however, indication is supplement. Please consider updating to Yes or provide explanation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:43:43
Query 'Per CDM: Response noted however, indication is supplement. Please consider updating to Yes or provide explanation.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	17 Nov 2020 21:52:18
DataPoint Un-verified.	Dawn Killian (b) (4) (b) (4)	17 Nov 2020 21:52:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	17 Nov 2020 21:52:04
User opened query 'Per CDM: Response noted however, indication is supplement. Please consider updating to Yes or provide explanation.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:30:04
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).		16 Nov 2020 20:30:04
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'indication is supplement.' (Site from DM).		05 Nov 2020 15:27:26
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).		05 Nov 2020 14:31:05
DataPoint Verified.		04 Nov 2020 21:10:48
User entered 'No (N)'		07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Supplement'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1500'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		07 Aug 2020 12:01:26
answered with 'Medication is ongoing, correct as entered.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 11:59:37
User entered 'un UNK 2016'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:04:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:04:13
Data point term sent to Coder	System	07 Aug 2020 12:03:38
User entered 'Duloxetine'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:36:57
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:05:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:05:10
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:31:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Depression'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '60'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:03:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:03:33
User entered 'un UNK 2017'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '2'	System	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	07 Aug 2020 22:20:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:20:13
Data point term sent to Coder	System	07 Aug 2020 12:05:38
User entered 'Gabapentin'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:37:06
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:06:45
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:32:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please update the indication to reflect the specific type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:37:28
Query 'Per DM CLR: Please update the indication to reflect the specific type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' answered with 'CORRECT AS IS PER PATIENT' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:06:58
User opened query 'Per DM CLR: Please update the indication to reflect the specific type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:32:19
User entered 'Diabetic peripheral neuropathy'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '300'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'three times daily (TID)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:05:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:05:21
User entered 'un UNK 2013'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '3'	System	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	14 Aug 2020 07:54:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 07:54:15
Data point term sent to Coder	System	07 Aug 2020 12:14:41
User entered 'Humalog'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:37:49
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:07:21
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:35:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Type 1 Diabetes'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Please remove and record the dose unit 'U' in the dose unit section. Please update dose and dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:11:00
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please remove and record the dose unit 'U' in the dose unit section. Please update dose and dose unit as appropriate.' answered with 'updated; per subject 100 IU is correct dose' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:44:12
User entered '100' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:43:41
User opened query 'Per DM CLR: Please remove and record the dose unit 'U' in the dose unit section. Please update dose and dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 02:24:19
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication (i.e., High dose). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		30 Sep 2020 09:38:04
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication (i.e., High dose). Please correct the dosage or provide explanation for alternate dosage.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:41
User entered 'U-100' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication (i.e., High dose). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:34:35
User entered '100'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'IU (IU)' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:43:41
User entered 'Other (OTHER)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User entered 'IU (IU)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:43:41
User entered 'UNITS' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'AC'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of DIABETES. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:11:03
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of DIABETES. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'UPDATED'' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:24:20
User entered empty; reason for change Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of DIABETES. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:35:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 13:42:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:52:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:14:08
User entered 'un UNK 1995'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	07 Aug 2020 12:16:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:16:13
Data point term sent to Coder	System	07 Aug 2020 12:15:42
User entered 'Levothyroxine'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:38:28
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:12:28
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:38:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Hypothyroid'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '175'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR-Requery: Response noted. However, Levothyroxine is recorded as UG/Micrograms/MCG. Please review if UG is more appropriate to be recorded. Please update the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:32:20
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR-Requery: Response noted. However, Levothyroxine is recorded as UG/Micrograms/MCG. Please review if UG is more appropriate to be recorded. Please update the unit as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:46:05
User entered 'ug (ug)' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:45:49
User opened query 'Per DM CLR-Requery: Response noted. However, Levothyroxine is recorded as UG/Micrograms/MCG. Please review if UG is more appropriate to be recorded. Please update the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:23:57
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM).		22 Oct 2020 06:23:57
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' answered with 'CORRECT PER PATIENT ' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:12:54
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:38:23
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:52:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:15:20
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 14:52:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 14:52:21
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4)	28 Oct 2020 19:48:19 28 Oct 2020 19:47:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 10:11:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 10:11:50
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4)	21 Sep 2020 20:25:33 21 Sep 2020 20:25:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 12:47:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 12:47:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	07 Aug 2020 12:16:42
User entered 'Lisinopril'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:47:59
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:25:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Please note this medication is not given as a prophylaxis. It is used to treat a condition. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:12:20
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).		11 Nov 2020 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'this drug can be used for prevention; correct as is' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:48:12
User entered 'KIDNEY DISEASE prevention' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:47:59
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:05:55
Query 'Per DM CLR: Please note this medication is not given as a prophylaxis. It is used to treat a condition. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:25:06
User entered 'KIDNEY DISEASE' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:25:01

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note this medication is not given as a prophylaxis. It is used to treat a condition. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:38:58
User entered 'Kidney prevention'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '20'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:51:51
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:16:23
User entered 'un UNK 2000'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: BRIMONIDINE TARTRATE;TIMOLOL MALEATE, PRODUCTSYNONYM: COMBIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:37:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:37:42
Data point term sent to Coder	System	21 Sep 2020 20:37:03
Data point term sent to Coder	System	21 Sep 2020 20:36:02
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:35:30
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: BRIMONIDINE TARTRATE;TIMOLOL MALEATE, PRODUCTSYNONYM: COMBIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:23:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:23:12
Data point term sent to Coder	System	07 Aug 2020 12:21:47
User entered 'Combigan'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:09
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:35:42
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:29:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:09:12
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:36:08
User entered 'BILATERAL GLAUCOMA' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:35:30
User opened query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:29:27
User entered 'Glaucoma'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '3'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'drops'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 12:51:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 12:51:18
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Aug 2020 12:51:18
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 12:21:34
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:09:15
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:36:37
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:36:27
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:29:06
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'OPHTHALMIC' reason for change:	Victoria Hernandez (b) (4)	21 Sep 2020 20:36:27
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:51:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:21:34
User entered 'un UNK 2007'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '2'	System	07 Aug 2020 12:51:18
User entered empty.	System	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:51:18
User entered empty.	System	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 12:51:18
User entered empty.	System	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST;NETARSUDIL MESILATE, PRODUCTSYNONYM: ROCKLATAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:38:45
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4)	21 Sep 2020 20:38:04 21 Sep 2020 20:37:22
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST;NETARSUDIL MESILATE, PRODUCTSYNONYM: ROCKLATAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Aug 2020 12:25:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:25:20
Data point term sent to Coder User entered 'Rocklatan'	System (b) (4), (b) (6)	07 Aug 2020 12:23:48 07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query ' Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query '	(b) (4), (b) (6)	30 Sep 2020 09:41:27
Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:37:22
User opened query ' Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:39:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:41:34
Query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:35
User entered 'BILATERAL GLAUCOMA' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:22
User opened query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:39:20
User entered 'Glaucoma'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '3'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'drops'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:41:39
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:39
User entered 'Other (OTHER)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:22
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:39:30
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'OPHTHALMIC' reason for change:	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:22
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:49:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:23:29
User entered 'un UNK 2007'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '2'	System	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Please review and provide the strength in the medication name as there are varying drug strength for this medication. Review and update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:35
DataPoint Un-verified.		06 Nov 2020 18:11:26
DataPoint Verified.		04 Nov 2020 21:35:43
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\202003.	(b) (4)	22 Sep 2020 01:42:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 01:42:47
Data point term sent to Coder	System	21 Sep 2020 20:40:09
Query 'Per DM CLR: Please review and provide the strength in the medication name as there are varying drug strength for this medication. Review and update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:39:49
User entered 'LATANOPROST 0.005%' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:39:44
Data point term sent to Coder	System	21 Sep 2020 20:39:08
Coding entries removed.	Victoria Hernandez (b) (4)	21 Sep 2020 20:38:52
User opened query 'Per DM CLR: Please review and provide the strength in the medication name as there are varying drug strength for this medication. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:36:24

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:36:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:36:14
Data point term sent to Coder	System	07 Aug 2020 12:34:50
User entered 'Latanoprost'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:44:10
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:39:56
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:36:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query ' Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). Query '	(b) (4), (b) (6)	30 Sep 2020 09:44:13
Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:40:00
User entered 'BILATERAL GLAUCOMA' reason for change: Data Entry Error	(b) (4)	
User opened query ' Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:36:16
User entered 'Glaucoma'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '2'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'drops'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:44:38
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:40:06
User entered 'Other (OTHER)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:38:52
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:36:49
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'OPHTHALMIC' reason for change:	Victoria Hernandez (b) (4)	21 Sep 2020 20:38:52
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:42:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:49:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:34:32
User entered 'un UNK 2007'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:45:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:45:57
Data point term sent to Coder	System	21 Sep 2020 20:45:17
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:44:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:29:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:29:17
Data point term sent to Coder	System	07 Aug 2020 12:35:51
User entered 'Tramadol'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:44:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:45:14
Query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:45:20
User entered 'LEFT KNEE PAIN' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:44:57
User opened query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:53:06
Query 'Per DM CLR: Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' canceled (Site from DM).		21 Sep 2020 06:52:01

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM). User entered 'Pain'	(b) (4), (b) (6)	21 Sep 2020 04:43:45
	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 21:36:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:45:30
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UPDATED ' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:45:25
User entered '100' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:44:57
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:44:04
User entered '1'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 21:36:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:44:57
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:43:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:48:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:35:41
User entered 'un UNK 2007'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 00:14:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 00:14:10
Data point term sent to Coder	System	07 Aug 2020 12:37:51
User entered 'Ergocalciferol'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:45:45
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' answered with 'UDPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:45:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:45:39
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:31:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Vitamin D deficiency'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1.25'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'every week (QS)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:43:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:48:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:37:39
User entered 'un UNK 2019'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '803 (803)'	System	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 10:34:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 10:34:39
Data point term sent to Coder	System	21 Sep 2020 20:49:24
Coding entries removed.	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Sep 2020 07:47:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Sep 2020 07:47:47
Data point term sent to Coder	System	11 Sep 2020 21:01:15
User closed query 'DM-Coding: please check spelling and update this term in accordance with your answer.' (Site from System).	System	11 Sep 2020 21:00:29
Query 'DM-Coding: please check spelling and update this term in accordance with your answer.' answered with 'UPDATED' (Site from System).	Victoria Hernandez (b) (4)	11 Sep 2020 21:00:29
User entered 'DOXYCYCLINE' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	11 Sep 2020 21:00:16
User opened query 'DM-Coding: please check spelling and update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4)	17 Aug 2020 08:12:17
Data point term sent to Coder	System	07 Aug 2020 12:41:53
User entered 'Doxycycmono'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is trying to prevent or treat (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:10:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is trying to prevent or treat (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:09
User entered 'DENTAL INFECTION' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:49:04
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is trying to prevent or treat (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:29:58
User entered 'Used before dental work'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '100'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
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).	(b) (4), (b) (6)	13 Nov 2020 23:03:57
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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 'CORRECT PER PATIENT' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:24
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), (b) (6)	21 Sep 2020 04:30:09
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:43:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:48:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:41:30
User entered 'un UNK 2016'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please review and confirm the status of this medication as it is unexpected to be ongoing for a long period of time. Review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:50:26
Query 'Per DM CLR: Please review and confirm the status of this medication as it is unexpected to be ongoing for a long period of time. Review and update as appropriate. Otherwise, clarify.' answered with 'ONLY TAKES FOR DENTAL PROCEDURES' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:40
User opened query 'Per DM CLR: Please review and confirm the status of this medication as it is unexpected to be ongoing for a long period of time. Review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:30:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 03:53:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 03:53:51
Data point term sent to Coder	System	28 Oct 2020 19:50:24
Coding entries removed.	Dawn Killian (b) (4)	28 Oct 2020 19:49:30
User entered 'TRIAMCINOLONE 0.025%' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:49:30
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:08:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:08:44
Data point term sent to Coder	System	21 Sep 2020 20:51:25
Coding entries removed.	Victoria Hernandez (b) (4)	21 Sep 2020 20:51:06

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:20
Data point term sent to Coder	System	07 Aug 2020 12:45:54
User entered 'Triamcinolone'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:33:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:49:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:49:30
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:13:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please update the indication to reflect the specific type of RASH. Please reconcile with the Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:51:16
Query 'Per DM CLR: Please update the indication to reflect the specific type of RASH. Please reconcile with the Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:51:14
User entered 'FACIAL ATOPIC DERMATITIS' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:51:06
User opened query 'Per DM CLR: Please update the indication to reflect the specific type of RASH. Please reconcile with the Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:45:36
User entered 'Rash to face'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:33:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' answered with 'updaetd' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:49:41
User entered '1' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:49:30
User opened query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:14:16
Query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' canceled (Site from DM).		21 Oct 2020 09:14:07

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:13:59
User closed query ' Per DM CLR: Please note, 0.025 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' (Site from DM).		21 Oct 2020 09:13:59
Query ' Per DM CLR: Please note, 0.025 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:51:19
User opened query ' Per DM CLR: Please note, 0.025 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:45:46
User entered '0.025%'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'application' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:49:30
User entered 'TOPICAL' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:51:06
User entered 'percent'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:48:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:45:34
User entered 'un UNK 2009'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:58:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:58:24
Data point term sent to Coder	System	07 Aug 2020 12:46:55
User entered 'Glucose tablets'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:52:19
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:52:51
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Type 1 Diabetes'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:52:27
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:52:55
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 04:33:03
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:33:03
User entered '1'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'g (g)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:52:39
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:43:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:47:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 12:46:51
User entered 'un UNK 1999'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered empty.	System	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	07 Oct 2020 16:24:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:24:21
Data point term sent to Coder	System	07 Oct 2020 16:23:58
Data point term sent to Coder	System	07 Oct 2020 16:22:55
Coding entries removed.	(b) (4), (b) (6)	07 Oct 2020 16:22:52
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)	25 Sep 2020 07:56:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 07:56:41
Data point term sent to Coder	System	24 Sep 2020 14:10:11
User entered 'Influenza Vaccine'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per CDM: Please review Indication and update to provide the medical condition that this medication was used to prevent. Please update to reflect Prophylaxis and the medical condition prevented as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:35:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per CDM: Please review Indication and update to provide the medical condition that this medication was used to prevent. Please update to reflect Prophylaxis and the medical condition prevented as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 16:24:10
User entered 'influenza' reason for change: Data Entry Error		07 Oct 2020 16:23:56
User entered 'influenza prophylaxis' reason for change: Data Entry Error		07 Oct 2020 16:22:52
User opened query 'Per CDM: Please review Indication and update to provide the medical condition that this medication was used to prevent. Please update to reflect Prophylaxis and the medical condition prevented as appropriate. Otherwise, clarify.' (Site from DM).		02 Oct 2020 22:16:31
User entered 'Non study vaccine'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '.5'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:35:50
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:51:22
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:50:03
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:58:05
User entered 'mg (mg)'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '23 Sep 2020'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '23 Sep 2020'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User entered empty.	System	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User entered empty.	System	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:25
User entered empty.	System	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE IN WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:00:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:00:23
Data point term sent to Coder	System	03 Nov 2020 23:57:34
User entered 'Dextrose 5% in water'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1000'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User entered empty.	System	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User entered empty.	System	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:30
User entered empty.	System	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 12:33:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 12:33:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Data point term sent to Coder	System	03 Nov 2020 23:59:36
User entered 'Insulin Regular 100 units + sodium chloride 0.9%'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '100'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User entered empty.	System	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User entered empty.	System	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:34
User entered empty.	System	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 05:14:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 05:14:20
Data point term sent to Coder	System	04 Nov 2020 00:02:02
User entered 'insulin regular human recomb 100 units/mL'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'UNK'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'UNKNOWN'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User entered empty.	System	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User entered empty.	System	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:38
User entered empty.	System	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM BICARBONATE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:58:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:58:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Data point term sent to Coder	System	04 Nov 2020 00:06:03
User entered 'Sodium Chloride 0.45% + Sodium Bicarbonate 8.4% 50 mEq'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1000'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User entered empty.	System	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User entered empty.	System	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:42
User entered empty.	System	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:16:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:16:51
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:29:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:29:16
Data point term sent to Coder	System	04 Nov 2020 00:08:04
User entered 'Sodium Chloride 0.9%'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '2000'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User entered empty.	System	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User entered empty.	System	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:53:46
User entered empty.	System	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:37:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:37:25
Data point term sent to Coder	System	29 Mar 2021 15:51:16
User entered 'Ceftriaxone'	Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'End stage congestive heart failure'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'l'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'g (g)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'once (ONCE)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '19 Dec 2020'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '19 Dec 2020'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
User entered empty.	System	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
User entered empty.	System	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:28
User entered empty.	System	29 Mar 2021 15:50:46

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:54:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:54:33
Data point term sent to Coder	System	29 Mar 2021 15:52:17
User entered 'Piperacillin-Tazobactam'	Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'End stage congestive heart failure'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '2.25'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'g (g)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'once (ONCE)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '19 Dec 2020'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '19 Dec 2020'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
User entered empty.	System	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
User entered empty.	System	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:54:31
User entered empty.	System	29 Mar 2021 15:52:16

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 00:53:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:53:25
Data point term sent to Coder	System	29 Mar 2021 15:59:36
User entered 'Doxycycline'	Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'End stage congestive heart failure'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '100'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'mg (mg)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'three times daily (TID)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Other (OTHER)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Nasogastric tube'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'UN Jan 2021'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'UN Jan 2021'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:08
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '3'	System	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	29 Mar 2021 15:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 16:01:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 16:01:06
Data point term sent to Coder	System	29 Mar 2021 16:00:38
User entered 'Zosyn'	Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'End stage congestive heart failure'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '3.375'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'g (g)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'three times daily (TID)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'UN Jan 2021'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'un Jan 2021'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:53:10
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '3'	System	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered 'I'	System	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:26:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '804 (804)'	System	29 Mar 2021 15:59:55

US3292023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:26:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:06
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Signature has been broken.	(b) (4)	
	Dawn Killian (b) (4)	24 Mar 2021 19:59:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	24 Mar 2021 19:59:05
User signature succeeded.	(b) (4)	
	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered 'No (N)'	(b) (4)	
	Dawn Killian (b) (4)	04 Feb 2021 15:51:35
	(b) (4)	

US3292023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:26:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:17
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '30 Nov 2020'	(b) (4) Dawn Killian (b) (4) (b) (4)	24 Mar 2021 19:59:25

US3292023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:26:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:17
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Tooth Extraction'	(b) (4) Dawn Killian (b) (4) (b) (4)	24 Mar 2021 19:59:25

US3292023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:26:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:17
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Adverse Event (AE)'	(b) (4) Dawn Killian (b) (4) (b) (4)	24 Mar 2021 19:59:25

US3292023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:26:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:17
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	24 Mar 2021 19:59:25

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:26:49

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:08:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '24 Jan 2021'	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:35:14

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:26:49

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:08:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'Death (DEATH)'	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:35:14

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:26:49

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:08:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:35:14

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:26:49

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:08:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User closed query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'Adverse event (ADVERSE EVENT) reason for change: Data Entry Error'	System	24 Mar 2021 20:01:33
User opened query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	Dawn Killian (b) (4)	24 Mar 2021 20:01:33
User entered empty.	(b) (4)	
	System	25 Feb 2021 22:35:14
	Gerardo Pena (b) (4)	25 Feb 2021 22:35:14
	(b) (4)	

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:26:49

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:08:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered empty.	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:35:14

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:26:49

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:08:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '24 Jan 2021'	(b) (4) Gerardo Pena (b) (4)	25 Feb 2021 22:35:14

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:26:49

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:08:05
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User closed query 'Reason for discontinuation is Death, however response to was autopsy performed is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	24 Mar 2021 20:01:33
User opened query 'Reason for discontinuation is Death, however response to was autopsy performed is missing. Please provide.' (Site from System).	Dawn Killian (b) (4)	24 Mar 2021 20:01:33
User entered empty.	(b) (4)	
	System	25 Feb 2021 22:35:14
	Gerardo Pena (b) (4)	25 Feb 2021 22:35:14
	(b) (4)	

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'USA-US072-2020-MRNA-1273-P301000007'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Douglas'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Denham'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '7940 Floyd Curl Drive'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'San Antonio'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '78229'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered 'US'	System	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '2'	System	25 Mar 2021 14:53:53
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered '1'	(b) (4) System	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'USA-US072-2020-MRNA-1273-P301000007'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Douglas'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Denham'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '7940 Floyd Curl Drive'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'San Antonio'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '78229'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered 'US'	System	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '2'	System	25 Mar 2021 14:53:53
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered '1'	(b) (4) System	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:26:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered '28/Oct/2020 13:21'	System	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:26:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered 'l'	(b) (4), (b) (6)	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'USA-US072-2020-MRNA-1273-P301000007'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Douglas'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Denham'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '7940 Floyd Curl Drive'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'San Antonio'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '78229'	System	28 Oct 2020 17:21:27

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered 'US'	System	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '2'	System	25 Mar 2021 14:53:53
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:00:31
User entered '1'	(b) (4) System	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:26:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:29
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '25/Mar/2021 10:53'	(b) (4) System	25 Mar 2021 14:53:53

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:26:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:29
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'l'	(b) (4), (b) (6)	25 Mar 2021 14:53:53

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	Ashlee Derr (6368 - aDerr1)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'USA-US072-2021-MRNA-1273-P301000014'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:32
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:34
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:36
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
Reviewed for Safety.		26 Mar 2021 16:03:37
Un-reviewed for Safety.	System	09 Mar 2021 23:05:06
Signature has been broken.	System	09 Mar 2021 23:05:06
User entered 'Yes (Y)'	System	09 Mar 2021 23:05:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:38
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:39
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:40
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	(b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:42
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Douglas'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:44
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Denham'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:45
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '7940 Floyd Curl Drive'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:47
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'San Antonio'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:49
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '78229'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:50
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:23:25
User entered 'US'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '6'	System	19 Apr 2021 15:29:38
User entered '5'	System	30 Mar 2021 14:26:25
User entered '4'	System	26 Mar 2021 16:04:04
User entered '3'	System	10 Mar 2021 14:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 20:23:34
User entered '1'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:29
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'USA-US072-2021-MRNA-1273-P301000014'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:31
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:32
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:34
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:36
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Reviewed for Safety.		26 Mar 2021 16:03:42
Un-reviewed for Safety.		26 Mar 2021 16:03:37
Signature has been broken.	System	09 Mar 2021 23:05:06
User entered 'Yes (Y)'	System	09 Mar 2021 23:05:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:09:31
	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:38
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:39
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:40
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:42
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Douglas'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:44
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Denham'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:45
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '7940 Floyd Curl Drive'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:47
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'San Antonio'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:49
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '78229'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:50
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:23:25
User entered 'US'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '6'	System	19 Apr 2021 15:29:38
User entered '5'	System	30 Mar 2021 14:26:25
User entered '4'	System	26 Mar 2021 16:04:04
User entered '3'	System	10 Mar 2021 14:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 20:23:34
User entered '1'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:26:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
User entered '22/Feb/2021 15:09'	(b) (4) System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:26:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:54
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:23:25
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:29
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	(b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'USA-US072-2021-MRNA-1273-P301000014'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:31
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:32
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:34
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:36
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
Reviewed for Safety.		26 Mar 2021 16:03:37
Un-reviewed for Safety.	System	09 Mar 2021 23:05:06
Signature has been broken.	System	09 Mar 2021 23:05:06
User entered 'Yes (Y)'	System	09 Mar 2021 23:05:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:38
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:39
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:40
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:42
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Douglas'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:44
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Denham'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:45
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '7940 Floyd Curl Drive'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:47
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'San Antonio'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:49
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '78229'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:50
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:23:25
User entered 'US'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '6'	System	19 Apr 2021 15:29:38
User entered '5'	System	30 Mar 2021 14:26:25
User entered '4'	System	26 Mar 2021 16:04:04
User entered '3'	System	10 Mar 2021 14:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 20:23:34
User entered '1'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:26:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:55
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
User entered '22/Feb/2021 15:23'	(b) (4) System	22 Feb 2021 20:23:34

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:26:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:55
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
Reviewed for Safety.		26 Mar 2021 16:03:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
User entered 'l'	(b) (4), (b) (6)	22 Feb 2021 20:23:34

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:29
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'USA-US072-2021-MRNA-1273-P301000014'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:31
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:32
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:34
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:36
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
Reviewed for Safety.		26 Mar 2021 16:03:37
Un-reviewed for Safety.	System	09 Mar 2021 23:05:06
Signature has been broken.	System	09 Mar 2021 23:05:06
User entered 'Yes (Y)'	System	09 Mar 2021 23:05:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:38
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:39
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:40
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:42
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Douglas'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:44
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Denham'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:45
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '7940 Floyd Curl Drive'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:47
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'San Antonio'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:49
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '78229'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:50
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:23:25
User entered 'US'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '6'	System	19 Apr 2021 15:29:38
User entered '5'	System	30 Mar 2021 14:26:25
User entered '4'	System	26 Mar 2021 16:04:04
User entered '3'	System	10 Mar 2021 14:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 20:23:34
User entered '1'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:26:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:57
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '10/Mar/2021 06:48'	(b) (4) System	10 Mar 2021 14:48:15

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:26:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:57
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Reviewed for Safety.		26 Mar 2021 16:03:42
User entered 'l'		26 Mar 2021 16:03:37
		10 Mar 2021 14:48:15

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:29
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'USA-US072-2021-MRNA-1273-P301000014'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:31
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:32
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:34
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:36
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
Reviewed for Safety.		26 Mar 2021 16:03:37
Un-reviewed for Safety.	System	09 Mar 2021 23:05:06
Signature has been broken.	System	09 Mar 2021 23:05:06
User entered 'Yes (Y)'	System	09 Mar 2021 23:05:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:38
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:39
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:40
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:42
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Douglas'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:44
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Denham'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:45
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '7940 Floyd Curl Drive'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:47
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'San Antonio'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:49
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '78229'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:50
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	(b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:23:25
User entered 'US'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '6'	System	19 Apr 2021 15:29:38
User entered '5'	System	30 Mar 2021 14:26:25
User entered '4'	System	26 Mar 2021 16:04:04
User entered '3'	System	10 Mar 2021 14:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 20:23:34
User entered '1'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:26:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '26/Mar/2021 12:04'	(b) (4) System	26 Mar 2021 16:04:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:26:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:58
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 14:24:34
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 16:04:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:29
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'USA-US072-2021-MRNA-1273-P301000014'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:31
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:32
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:34
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:36
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
Reviewed for Safety.		26 Mar 2021 16:03:37
Un-reviewed for Safety.	System	09 Mar 2021 23:05:06
Signature has been broken.	System	09 Mar 2021 23:05:06
User entered 'Yes (Y)'	System	09 Mar 2021 23:05:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:38
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:39
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:40
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:42
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Douglas'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:44
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Denham'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:45
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '7940 Floyd Curl Drive'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:47
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'San Antonio'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:49
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '78229'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:50
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:23:25
User entered 'US'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '6'	System	19 Apr 2021 15:29:38
User entered '5'	System	30 Mar 2021 14:26:25
User entered '4'	System	26 Mar 2021 16:04:04
User entered '3'	System	10 Mar 2021 14:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 20:23:34
User entered '1'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:26:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:46:00
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered '30/Mar/2021 10:26'	(b) (4) System	30 Mar 2021 14:26:25

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:26:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
Reviewed for Safety.		19 Apr 2021 15:29:25
DataPoint Verified.		16 Apr 2021 15:46:00
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:26:25

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:29
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'USA-US072-2021-MRNA-1273-P301000014'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:31
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:32
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Yes (Y)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:34
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:36
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:07:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
Reviewed for Safety.		26 Mar 2021 16:03:37
Un-reviewed for Safety.	System	09 Mar 2021 23:05:06
Signature has been broken.	System	09 Mar 2021 23:05:06
User entered 'Yes (Y)'	System	09 Mar 2021 23:05:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:38
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:39
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:40
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'No (N)'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:42
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Douglas'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:44
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'Denham'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:45
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '7940 Floyd Curl Drive'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:47
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered 'San Antonio'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:49
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:09:31
User entered '78229'	System	22 Feb 2021 20:08:49

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
DataPoint Verified.		16 Apr 2021 15:45:50
Reviewed for Safety.		26 Mar 2021 16:03:46
Un-reviewed for Safety.		26 Mar 2021 16:03:42
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 20:23:25
User entered 'US'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User entered '6'	System	19 Apr 2021 15:29:38
User entered '5'	System	30 Mar 2021 14:26:25
User entered '4'	System	26 Mar 2021 16:04:04
User entered '3'	System	10 Mar 2021 14:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 20:58:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 20:23:34
User entered '1'	System	22 Feb 2021 20:09:59

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:26:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:45:41
User entered '19/Apr/2021 11:29'	(b) (4) System	19 Apr 2021 15:29:38

US3292023

Folder: SAE USA-US072-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:26:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:04
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:45:41
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 15:29:38