

US3812132 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:50:14

All time stamps listed in this document are displayed in GMT

US3812132

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

[Participant ID](#)

US3812132

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

US3812132

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 04:39:54

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Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 04:39:54

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 04:39:54

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Condition	ERYTHROCYTOSIS
Start date (dd MMM yyyy)	03 FEB 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	HYPERTENSION
Start date (dd MMM yyyy)	25 AUG 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	DEPRESSION
Start date (dd MMM yyyy)	25 AUG 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812132

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	21 AUG 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	OBESITY
Start date (dd MMM yyyy)	11 JAN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	TESTICULAR HYPOFUNCTION
Start date (dd MMM yyyy)	25 AUG 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	MODERATE PERSISTENT ASTHMA WITH ACUTE EXACERBATION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	03 FEB 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812132

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	LEFT ANKLE BREAK
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (11)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	LEFT ANKLE SURGERY
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (12)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	SINUS SURGERY
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (13)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	LEFT TORN CRUCIATE LIGAMENT
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	LEFT CRUCIATE LIGAMENT TORN-REPAIR
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	GALLBLADDER REMOVAL
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	GALLBLADDER INFLAMMATION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	PENICILLIN ALLERGY (ANAPHYLACTIC)
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	LEFT BROKEN HAND
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1968
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	JAN 1968
Stop Year (derived)	1968

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	LEFT BROKEN HAND SURGERY
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1968
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	JAN 1968
Stop Year (derived)	1968

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	PAST SMOKER
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

US3812132

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	OSTEOARTHRITIS BILATERAL HANDS
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3812132

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	BILATERAL RESTLESS LEGS SYNDROME
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (26)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

US3812132

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:39:54

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Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:09
Height (xxx.x)	68.0 in
Weight (xxx.x)	243.6 lb
BMI (xxx.x)	37.11670 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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) 15 Feb 2021 04:39:54

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:39:54

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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)	False
Other	True
Specify	SOCIAL BEHAVIOR;RECENT TRAVEL ON PLANE

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:39:55

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Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185594

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) 15 Feb 2021 04:39:55

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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) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:09
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	17:47 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 17:47
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
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)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:39:55

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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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 17:14 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 17:14

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

What was the frequency of the study treatment dosing? ONCE

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

US3812132

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

17:07 (24 HR)

Collection date and time (derived)

11 AUG 2020 17:07

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:09	11 AUG 2020 17:09
Nasopharyngeal Swab 2	No		

US3812132

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 17:53

PC Open Date & Time

11 AUG 2020 17:34

PC Close Date & Time

11 AUG 2020 20:04

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	11 AUG 2020 21:30
PC Open Date & Time	11 AUG 2020 20:59
PC Close Date & Time	12 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:32

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

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

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 13 AUG 2020 12:36

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

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

14 AUG 2020 17:53

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:38

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

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

16 AUG 2020 14:45

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:43

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

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

11 AUG 2020 17:54

PC Open Date & Time

11 AUG 2020 17:34

PC Close Date & Time

11 AUG 2020 20:04

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

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

11 AUG 2020 21:31

PC Open Date & Time

11 AUG 2020 20:59

PC Close Date & Time

12 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

12 AUG 2020 13:36

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

10

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

13 AUG 2020 12:37

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

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

14 AUG 2020 17:54

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

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

15 AUG 2020 19:39

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

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

16 AUG 2020 14:45

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

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

17 AUG 2020 12:43

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

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 ☐

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 17:55
PC Open Date & Time	11 AUG 2020 17:34
PC Close Date & Time	11 AUG 2020 20:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

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 ☐

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 21:32
PC Open Date & Time	11 AUG 2020 20:59
PC Close Date & Time	12 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	12 AUG 2020 13:37
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

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)

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	13 AUG 2020 12:38
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

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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US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	14 AUG 2020 17:55
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	15 AUG 2020 19:39
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	16 AUG 2020 14:46
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	17 AUG 2020 12:43
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3812132

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

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

US3812132

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:33
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 13:29
Temperature (xxx.x)	96.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3812132

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

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.

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 12:58 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 12:58

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

US3812132

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	8 SEP 2020 12:45

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:48	8 SEP 2020 12:48
Nasopharyngeal Swab 2	No		

US3812132

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 13:39

PC Open Date & Time

08 SEP 2020 13:18

PC Close Date & Time

08 SEP 2020 15:48

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	08 SEP 2020 21:08
PC Open Date & Time	08 SEP 2020 16:43
PC Close Date & Time	09 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 09 SEP 2020 12:25

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	10 SEP 2020 14:27
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 14:18

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 15:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

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

97.1 °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

14 SEP 2020 14:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

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

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

08 SEP 2020 13:39

PC Open Date & Time

08 SEP 2020 13:18

PC Close Date & Time

08 SEP 2020 15:48

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

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

08 SEP 2020 21:10

PC Open Date & Time

08 SEP 2020 16:43

PC Close Date & Time

09 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

50

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

09 SEP 2020 12:26

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

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 ☐

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

90

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)**

110

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

10 SEP 2020 14:28

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 4
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)	140
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)	60
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	11 SEP 2020 14:20
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

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)**

170

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)**

70

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

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

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)**

150

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 15:47

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

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 ☐
Please record - REDNESS AT INJECTION SITE (in mm)	140
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
PC Time Stamp	14 SEP 2020 14:49
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

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 ☐

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 13:40
PC Open Date & Time	08 SEP 2020 13:18
PC Close Date & Time	08 SEP 2020 15:48

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

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 ☐

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 21:11
PC Open Date & Time	08 SEP 2020 16:43
PC Close Date & Time	09 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

114 of 2915

EAB) (1725)

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	09 SEP 2020 12:27
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

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

116 of 2915

EAB) (1725)

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	10 SEP 2020 14:29
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

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 ☒

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EAB) (1725)

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US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	11 SEP 2020 14:20
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	12 SEP 2020 12:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

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)

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	13 SEP 2020 15:48
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

Yes ☐	
PC Time stamp	14 SEP 2020 14:49
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 8
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
PC Time Stamp	15 SEP 2020 23:59
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3812132

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 SEP 2020 00:00
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3812132

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 11:28
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812132

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

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.

US3812132

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	11:40 (24 HR)
Collection date and time (derived)	5 OCT 2020 11:40

US3812132

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:40:24

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 OCT 2020 00:01:54

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

20 OCT 2020 11:49:22

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

25 OCT 2020 10:41:16

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 15:46:29

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

15 NOV 2020 00:10:33

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 01:03:25

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 12:02:17

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 09:40:13

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 00:32:24
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 15:17:22

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 00:09:44

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	31 DEC 2020 00:24:46
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 08:10:42
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 13:42:12
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 09:35:45

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 10:34:45

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	08 FEB 2021 09:48:35
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 12:45:27
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 08:30:32

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 13:29:52
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 01:00:27

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 11:13:13

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 04:27:39

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 08:43:32

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 08:10:51

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 00:05:14

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 08:29:21

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:02:38

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

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02 AUG 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

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30 AUG 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

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13 SEP 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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24 JAN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

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07 FEB 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

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14 FEB 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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Date and time of submission

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17 FEB 2022 00:01

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21 FEB 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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Date and time of submission

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US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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Date and time of submission

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21 MAR 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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Date and time of submission

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24 MAR 2022 00:01

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28 MAR 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

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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 MAR 2022 00:01

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04 APR 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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07 APR 2022 00:01

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11 APR 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

US3812132

Folder: New Safety Follow Up Diary (1)

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14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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21 APR 2022 00:01

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25 APR 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

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13 JUN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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25 JUL 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 789

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

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

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

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

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3812132

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:50:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 09:12:11

US3812132

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 MAR 2021
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 13:30
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812132

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:58:27

Generated On: 10 Jun 2021 09:50:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3812132

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:58:27

Generated On: 10 Jun 2021 09:50:14

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	13:48 (24 HR)
Collection date and time (derived)	24 MAR 2021 13:48

US3812132

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:58:27

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812132

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812132

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812132

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:50:14

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3812132

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:58:23

Generated On: 10 Jun 2021 09:50:14

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	4 MAR 2021

Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒

Folder OID	UNBLND_DECIDE

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Date of updated informed consent (<i>dd MMM yyyy</i>)	4 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (<i>dd MMM yyyy</i>)	4 MAR 2021
Participant randomization assignment	mRNA-1273 ☒ Placebo ☐
Actual Dose 1	mRNA-1273 ☒ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☒ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☒
Placebo Only Flag	☐
Continuing with mRNA-1273	☐

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:58:23

Generated On: 10 Jun 2021 09:50:14

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	4 MAR 2021 12:00

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 01:58:23

Generated On: 10 Jun 2021 09:50:14

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00 - 23:59)	12:03
Collection Date and Time (derived)	4 MAR 2021 12:03

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Visit Date	14 SEP 2020

Please check all assessments that apply for this visit

Physical Exam	True

Vital Signs	True

Immunogenicity Assessment	False

Pregnancy Test	False

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:39:55

Generated On: 10 Jun 2021 09:50:14

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 14:35
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3812132

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

AEID

Adverse event

WORSENING ANXIETY

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 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	_____

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

AEID

Adverse event

WORSENING GERD

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 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	_____

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

AEID

Adverse event

DERMATITIS ON LEFT ARM

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)

09 SEP 2020

Start time (00:00-23:59)

09:00 (24 HR)

AE start date and time (derived)

09 SEP 2020 09:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 SEP 2020

End time (00:00-23:59)

09:00 (24 HR)

AE End Date and Time (derived)

17 SEP 2020 09:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

AEID

Adverse event

WORSENING ANXIETY

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)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	_____

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

AEID

Adverse event

BRONCHITIS

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)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	_____

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

AEID	USA-US101-2021-MRNA-1273-P30 1000004
Adverse event	WORSENING OBESITY
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)	24 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	26 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	26 DEC 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

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 ☒
	Related ☐
	Not Applicable ☐
Relationship to Study Procedure	Not Related ☒
	Related ☐
	Not Applicable ☐
Action taken with investigational product	None ☐
	Dose Delayed ☐
	Investigational Product ☐
	Withdrawn ☐
	Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐
	Not Recovered/Not Resolved ☐
	Recovered/Resolved ☒
	Recovered/Resolved with Sequelae ☐
	Recovering/Resolving ☐
	Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

	SUBJECT ADMITTED 24DEC2020 FOR GASTRIC SLEEVE SURGERY. WAS HOSPITALIZED UNTIL 26DEC2020. PER SUBJECT HOSPITAL COURSE UNEVENTFUL. DISCHARGE RECORDS PENDING
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

AEID	USA-US101-2021-MRNA-1273-P30 1000006
Adverse event	ABSCCESS (POST SURGICAL ABDOMINAL)
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)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	06 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	06 FEB 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

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 ☒
	Related ☐
	Not Applicable ☐
Relationship to Study Procedure	Not Related ☒
	Related ☐
	Not Applicable ☐
Action taken with investigational product	None ☐
	Dose Delayed ☐
	Investigational Product ☐
	Withdrawn ☐
	Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐
	Not Recovered/Not Resolved ☐
	Recovered/Resolved ☒
	Recovered/Resolved with Sequelae ☐
	Recovering/Resolving ☐
	Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 26 Apr 2021 16:36:54

Generated On: 10 Jun 2021 09:50:14

SUBJECT DEVELOPED ABSCESS
NEAR PREVIOUS SURGICAL
INCISION. FAMILY MEMBER
TRIED TO DRAIN ON 29JAN2021,
WENT TO ER 30JAN2021 AND
WAS ADMITTED FOR IV
ANTIBIOTICS AND DRAIN
PLACEMENT. DISCHARGED
WITH PO AND IV ANTIBIOTICS
FOR 1 WEEK ON 06FEB2021.
RECORDS PENDING

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

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 01:58:23

Generated On: 10 Jun 2021 09:50:14

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration .5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	26 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication TAMULUSIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE PROSTATE
HEALTH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS IN BOTH HANDS

Dose per administration 200

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 (6)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication BUPOPION XL

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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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) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 20 FEB 2021		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication IRON

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 324

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 (9)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	24 DEC	2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication D3 (250MCG) / K2 (1500MCG)

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication XYZAL 24HR

Prophylaxis Yes ☐
No ☒

Indication ENVIRONMENTAL ALLERGIES

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 (12)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication QUERCETIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 800

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

6X/DAY

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) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 16:36:55

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Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☒
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication SYMBICORT [BUDESONIDE
80MCG, FORMOTEROL
FUMARATE DIHYDRATE
4.5MCG]

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☒
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	26	OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication AZELASTINE 0.15%

Prophylaxis Yes ☐
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 411

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) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify SPRAY/NOSTRIL

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) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication TESTOSTERONE CREAM

Prophylaxis Yes ☐
No ☒

Indication TESTICULAR HYPOFUNCTION

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify PUMPS

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 (18)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2011	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING ANXIETY

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 (19)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	08 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication EPIPEN

Prophylaxis Yes ☐
No ☒

Indication PENICILLIN ALLERGY

Dose per administration 0.3

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 (20)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication NEUPRO

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 3

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) 26 Apr 2021 16:36:55

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	24 FEB 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING GERD

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE AND PAIN AT
INJECTION SITE

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	11 SEP 2020	
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication ANORO ELLIPTA

Prophylaxis Yes ☐
No ☒

Indication BRONCHITIS

Dose per administration 62.5/25

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 (24)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication WORSENING ANXIETY

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 (25)

Data signed: (b) (4) 26 Apr 2021 16:36:55

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING ANXIETY

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication BARIATRIC MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication LINEZOLID

Prophylaxis Yes ☐
No ☒

Indication ABSCESS

Dose per administration 600

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Feb 2021 04:39:54

Generated On: 10 Jun 2021 09:50:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 DEC 2020	GASTRIC SLEEVE SURGERY	Adverse Event	
30 JAN 2021	ABSCESS DRAIN	Adverse Event	

US3812132

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:50:14

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

US3812132

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:50:14

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 01:58:27

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 01:58:27

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/JAN/2021 09:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 01:58:27

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/FEB/2021 12:52
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

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 01:58:27

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/MAR/2021 08:51
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

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/FEB/2021 08:28
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

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/MAR/2021 11:28
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

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/MAR/2021 10:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 16:36:55

Generated On: 10 Jun 2021 09:50:14

SAEID	USA-US101-2021-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/APR/2021 10:17
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

US3812132 (Prod: UIC Project WISH CRS)

US3812132

Form: Participant Creation

Generated On: 10 Jun 2021 09:50:14

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'US3812132'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:49:08

US3812132

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:04
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:29

US3812132

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:04
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:49:09

US3812132

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:04
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:29

US3812132

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'SCRN'	System	11 Aug 2020 22:31:29

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:49:10

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '72'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'YEARS'	System	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '72'	System	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered 'Male (M)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '1'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '0'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '0'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '0'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '0'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '0'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered empty.	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '0'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '0'	Heather Cherniawski (b) (4)	11 Aug 2020 22:33:49

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:55
User entered '11 Aug 2020'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Aug 2020'	System	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2020'	System	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:47:55
User entered 'Amendment 1 (1)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:55
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:55
User entered empty.	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:47:55
User entered empty.	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:55
User entered 'No (N)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:39

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:49:09

US3812132

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1'	System	11 Aug 2020 22:31:43

US3812132

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:50:14

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:48:20
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:43

US3812132

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:50:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:48:28
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:14:49

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Red blood cell disorders, HLT: Polycythaemia (excl rubra vera), PT: Polycythaemia, LLT: Erythrocytosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:16:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:16:39
Data point term sent to Coder	System	24 Aug 2020 14:15:25
User entered 'ERYTHROCYTOSIS'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '03 Feb 2015'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User closed query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:18:46
Query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page.' answered with 'NO MEDS LISTED FOR THIS CONDITION IN SOURCE OR MR' (Site from CRA).	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:45:35
User opened query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:08:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Feb 2015'	System	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2015'	System	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:15:11

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:17:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:17:44
Data point term sent to Coder	System	24 Aug 2020 14:16:28
User entered 'HYPERTENSION'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '25 Aug 2011'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Aug 2011'	System	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2011'	System	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:15:27

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
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) (b) (4)	24 Aug 2020 14:17:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:17:44
Data point term sent to Coder	System	24 Aug 2020 14:16:26
User entered 'DEPRESSION'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '25 Aug 2011'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4)	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Aug 2011'	System	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2011'	System	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:15:39

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:17:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:17:42
Data point term sent to Coder	System	24 Aug 2020 14:16:28
User entered 'ENVIRONMENTAL ALLERGIES'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'un UNK 1990' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:41:06
User entered '25 Aug 2011'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1990'	System	05 Oct 2020 14:41:06
User entered 'Aug 2011'	System	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1990'	System	05 Oct 2020 14:41:06
User entered '2011'	System	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:15:52

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:17:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:17:44
Data point term sent to Coder	System	24 Aug 2020 14:16:31
User entered 'OBSTRUCTIVE SLEEP APNEA'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '21 Aug 2018'	Breanna Galibert (b) (4)	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Aug 2018'	System	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2018'	System	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:16:21

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:18:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:18:32
Data point term sent to Coder	System	24 Aug 2020 14:17:31
User entered 'OBESITY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '11 Jan 2018'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2018'	System	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2018'	System	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:16:33

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Male gonadal function disorders, PT: Testicular failure, LLT: Hypofunction testicle - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:05:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:05:33
Data point term sent to Coder	System	24 Aug 2020 14:17:32
User entered "TESTICULAR HYPOFUNCTION"	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '25 Aug 2011'	Breanna Galibert (b) (4)	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4)	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Aug 2011'	System	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2011'	System	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:17:20

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Exacerbation of asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 07:29:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 07:29:46
Data point term sent to Coder	System	24 Aug 2020 14:18:34
User entered 'MODERATE PERSISTENT ASTHMA WITH ACUTE EXACERBATION'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'un UNK 1990' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:41:26
User entered '25 Aug 2011'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4)	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1990'	System	05 Oct 2020 14:41:26
User entered 'Aug 2011'	System	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1990'	System	05 Oct 2020 14:41:26
User entered '2011'	System	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:18:04

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
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.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:19:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:19:35
Data point term sent to Coder	System	24 Aug 2020 14:18:34
User entered 'VITAMIN D DEFICIENCY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '03 Feb 2015'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4)	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Feb 2015'	System	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2015'	System	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:18:22

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Broken ankle - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:02:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:02:41
Data point term sent to Coder	System	24 Aug 2020 14:19:35
User entered 'LEFT ANKLE BREAK'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2007'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2007'	Breanna Galibert (b) (4)	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2007'	System	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2007'	System	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2007'	System	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2007'	System	24 Aug 2020 14:18:36

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle operation, LLT: Ankle operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:20:41
Data point term sent to Coder	System	24 Aug 2020 14:19:35
User entered 'LEFT ANKLE SURGERY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2007'	Breanna Galibert (b) (4)	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2007'	Breanna Galibert (b) (4)	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2007'	System	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2007'	System	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2007'	System	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2007'	System	24 Aug 2020 14:18:51

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:20:41
Data point term sent to Coder	System	24 Aug 2020 14:19:37
User entered 'SINUS SURGERY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2007'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2007'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2007'	System	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2007'	System	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2007'	System	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2007'	System	24 Aug 2020 14:19:06

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:20:41
Data point term sent to Coder	System	24 Aug 2020 14:19:37
User entered 'SINUSITIS'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1965'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User closed query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:20:11
Query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page.' answered with 'PER MED SHEETS FLONASE, AZELASTINE PER INVESTIGATOR LD' (Site from CRA).	Maureen Dempsey (b) (4)	30 Oct 2020 22:40:32
User opened query 'Per ETRTR, Please confirm if subject is taking concomitant medication for this condition and ensure data is entered in Concomitant Medication page.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:11:22
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please be advised a procedure for this condition was recorded (MH#12 UN UNK 2007-UN UNK 2007). Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:55:31
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please be advised a procedure for this condition was recorded (MH#12 UN UNK 2007-UN UNK 2007). Please correct dates or provide explanation for the Med History duration.' answered with 'per subject condition still ongoing even after sinus surgery in 2007.' (Site from DM).	Anya Penly (b) (4)	02 Oct 2020 19:37:08
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please be advised a procedure for this condition was recorded (MH#12 UN UNK 2007-UN UNK 2007). Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:37:11

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1965'	System	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1965'	System	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:19:21

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 11:13:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 11:13:41
Data point term sent to Coder	System	24 Aug 2020 14:20:38
User entered 'LEFT TORN CRUCIATE LIGAMENT'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1999'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1999'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1999'	System	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1999'	System	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1999'	System	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1999'	System	24 Aug 2020 14:19:46

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ligament operation, LLT: Ligament operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:08:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:08:39
Data point term sent to Coder	System	24 Aug 2020 14:20:40
User entered 'LEFT CRUCIATE LIGAMENT TORN-REPAIR'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1999'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:09

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Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1999'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1999'	System	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1999'	System	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1999'	System	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1999'	System	24 Aug 2020 14:20:09

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Gallbladder removal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:21:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:21:33
Data point term sent to Coder	System	24 Aug 2020 14:20:40
User entered 'GALLBLADDER REMOVAL'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2018'	System	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2018'	System	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2018'	System	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2018'	System	24 Aug 2020 14:20:28

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Gallbladder inflammation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:22:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:22:37
Data point term sent to Coder	System	24 Aug 2020 14:21:41
User entered 'GALLBLADDER INFLAMMATION'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2018'	System	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2018'	System	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2018'	System	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2018'	System	24 Aug 2020 14:20:56

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:22:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:22:36
Data point term sent to Coder	System	24 Aug 2020 14:21:41
User entered 'ANXIETY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2015'	Breanna Galibert (b) (4)	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4)	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2015'	System	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2015'	System	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:21:06

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:22:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:22:37
Data point term sent to Coder	System	24 Aug 2020 14:21:42
User entered 'INSOMNIA'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1990'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1990'	System	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1990'	System	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:21:17

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Anaphylactic and anaphylactoid responses, PT: Anaphylactic reaction, LLT: Anaphylactic reaction to drug - version MedDRA\23.0.	Coder Import (b) (4)	24 Jan 2021 16:28:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Jan 2021 16:28:51
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:41:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:41:40
Data point term sent to Coder	System	24 Aug 2020 14:22:44
User entered 'PENICILLIN ALLERGY (ANAPHYLACTIC)'	Breanna Galibert (b) (4)	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1975'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1975'	System	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1975'	System	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:21:52

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hand fracture, LLT: Broken hand - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 10:29:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 10:29:49
Data point term sent to Coder	System	24 Aug 2020 14:22:45
User entered 'LEFT BROKEN HAND'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1968'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1968'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1968'	System	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1968'	System	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1968'	System	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1968'	System	24 Aug 2020 14:22:09

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:15:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:15:08
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Hand repair operation, LLT: Hand repair operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 21:06:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 21:06:30
Data point term sent to Coder	System	24 Aug 2020 14:22:45
User entered 'LEFT BROKEN HAND SURGERY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1968'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1968'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1968'	System	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1968'	System	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1968'	System	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1968'	System	24 Aug 2020 14:22:27

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Ex-tobacco user, LLT: Ex-smoker - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:40:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:40:37
Data point term sent to Coder	System	24 Aug 2020 14:22:45
User entered 'PAST SMOKER'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1975'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1980'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1975'	System	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1975'	System	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1980'	System	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1980'	System	24 Aug 2020 14:22:44

US3812132

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS IN (B) HANDS (Rheumatoid versus Osteoarthritis). 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)	11 Nov 2020 12:22:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 22:40:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 22:40:17
Data point term sent to Coder	System	30 Oct 2020 22:39:27
Query 'Per DM CLR: Please specify the type of ARTHRITIS IN (B) HANDS (Rheumatoid versus Osteoarthritis). 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).	Maureen Dempsey (b) (4)	30 Oct 2020 22:38:33
Coding entries removed.	Maureen Dempsey (b) (4)	30 Oct 2020 22:38:27
User entered 'OSTEOARTHRITIS BILATERAL HANDS' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	30 Oct 2020 22:38:27
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS IN (B) HANDS (Rheumatoid versus Osteoarthritis). 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)	22 Oct 2020 18:15:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Hand arthritis - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 18:03:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 18:03:37

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Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Aug 2020 14:23:49
User entered 'ARTHRITIS IN (B) HANDS'	Breanna Galibert (b) (4)	24 Aug 2020 14:23:09
	(b) (4)	

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Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2013'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:09

US3812132

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:23:09

US3812132

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:09

US3812132

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:09

US3812132

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:23:09

US3812132

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2013'	System	24 Aug 2020 14:23:09

US3812132

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2013'	System	24 Aug 2020 14:23:09

US3812132

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:23:09

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Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	24 Aug 2020 14:23:09

US3812132

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of RESTLESS LEGS SYNDROME. 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)	11 Nov 2020 12:22:47
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless legs syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 08:30:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 08:30:22
Data point term sent to Coder	System	30 Oct 2020 22:42:31
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of RESTLESS LEGS SYNDROME. 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).	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:41:37
Coding entries removed.	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:41:30
User entered 'BILATERAL RESTLESS LEGS SYNDROME' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:41:30
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of RESTLESS LEGS SYNDROME. 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)	28 Oct 2020 17:24:52
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless legs syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:31:42

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Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	30 Sep 2020 20:31:42
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 20:31:21
User entered 'Restless legs syndrome'	Breanna Galibert (b) (4)	30 Sep 2020 20:30:57
	(b) (4)	

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Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2019'	Breanna Galibert (b) (4)	30 Sep 2020 20:30:57

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Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	30 Sep 2020 20:30:57

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Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:30:57

US3812132

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:30:57

US3812132

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	30 Sep 2020 20:30:57

US3812132

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2019'	System	30 Sep 2020 20:30:57

US3812132

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2019'	System	30 Sep 2020 20:30:57

US3812132

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	30 Sep 2020 20:30:57

US3812132

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	30 Sep 2020 20:30:57

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:31:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:31:42
Data point term sent to Coder	System	30 Sep 2020 20:31:21
User entered 'SULFA ALLERGY'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:31:10

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Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 1975'	Breanna Galibert (b) (4)	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Breanna Galibert (b) (4)	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 1975'	System	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '1975'	System	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	30 Sep 2020 20:31:10

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 23:01:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 23:01:12
Data point term sent to Coder	System	30 Oct 2020 23:00:41
User entered 'GERD'	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'UN UNK 2019'	Maureen Dempsey (b) (4)	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Maureen Dempsey (b) (4)	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered 'Yes (Y)'	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered empty.	Maureen Dempsey (b) (4)	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:49:15
User entered '0'	Maureen Dempsey (b) (4)	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'Jan 2019'	System	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '2019'	System	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:50:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered empty.	System	30 Oct 2020 23:00:11

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered '11 Aug 2020'	Breanna Galibert (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered '15:09'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered '11 Aug 2020 15:09'	System	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered '68.0' in	Breanna Galibert (b) (4)	24 Aug 2020 14:23:56
DataPoint set to visible.	(b) (4) System	11 Aug 2020 22:31:43

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered '243.6' lb	Breanna Galibert (b) (4)	24 Aug 2020 14:23:56
DataPoint set to visible.	(b) (4) System	11 Aug 2020 22:31:43

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
Amendment Manager: User entered '37.11670'	System	16 Sep 2020 23:52:45
User entered '37.1'	System	24 Aug 2020 14:23:56
DataPoint set to visible.	System	11 Aug 2020 22:31:43

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'kg/m2'	System	24 Aug 2020 14:23:56
DataPoint set to visible.	System	11 Aug 2020 22:31:43

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User closed query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:08:53
Query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' answered with '-----corrected-----' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:37:26
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 19:37:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 19:37:22
User opened query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:45:59
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered 'Other (Other)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'bpm'	System	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'breaths/min'	System	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'mmHg'	System	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User entered 'mmHg'	System	24 Aug 2020 14:23:56

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41

US3812132

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41

US3812132

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:28
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:03

US3812132

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:53:28
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:29:55
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 18:26:50
User entered '11 Aug 2020'	Breanna Galibert (b) (4)	24 Aug 2020 14:24:03
	(b) (4)	

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '0'	Breanna Galibert (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

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 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '1'	Breanna Galibert (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:14:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:53:52
User entered 'SOCIAL BEHAVIOR;RECENT TRAVEL ON PLANE'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:24:53

US3812132

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:22
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:53

US3812132

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:22
User entered '11 Aug 2020'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:53

US3812132

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:22
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:31:53

US3812132

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'VISIT1'	System	11 Aug 2020 22:31:53

US3812132

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:14

[What was the date of randomization? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:33
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:49:16

US3812132

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:44:33
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:44:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 21:49:16
User entered '185594' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:49:16

US3812132

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:33
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:49:16

US3812132

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:14

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:33
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:25:53

US3812132

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:14

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:33
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:25:53

US3812132

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:14

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:33
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:25:53

US3812132

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:14

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:33
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:25:53

US3812132

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:33
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:25:53

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '11 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '15:09'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered '11 Aug 2020 15:09'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '97.4' F	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '70'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'bpm'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '16'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'breaths/min'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '134'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'mmHg'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '80'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'mmHg'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '11 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '17:47'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered '11 Aug 2020 17:47'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '98.2' F	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '68'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'bpm'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '14'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'breaths/min'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '128'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'mmHg'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:54:56
User entered '80'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'mmHg'	System	24 Aug 2020 14:27:22

US3812132

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:07
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:05

US3812132

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:07
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:05

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:21
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:21
User entered empty.	Heather Cherniawski (b) (4)	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:21
User entered empty.	Heather Cherniawski (b) (4)	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:21
User entered '11 Aug 2020'	Heather Cherniawski (b) (4)	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:21
User entered '17:14'	Heather Cherniawski (b) (4)	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered '11 Aug 2020 17:14'	System	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:21
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski (b) (4)	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:55:21
User entered 'ONCE'	System	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 22:32:13

US3812132

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:38
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:36

US3812132

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:38
User entered '11 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:36

US3812132

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:55:38
User entered '17:07'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:36

US3812132

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered '11 Aug 2020 17:07'	System	24 Aug 2020 14:27:36

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:50:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:56:22
User entered '11 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4)	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:56:22
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:56:22
User entered '17:09'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered '11 Aug 2020 17:09'	System	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:56:22
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:56:22
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered empty.	System	24 Aug 2020 14:27:59

US3812132

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:56:37
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:58

US3812132

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered '1'	System	24 Aug 2020 14:42:58

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:52:54', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '045c0790-9062-4dde-9f17-ac4f6f229257'	System	11 Aug 2020 22:53:28
User entered 'Yes (Y)'	System	11 Aug 2020 22:53:28

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:53:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '045c0790-9062-4dde-9f17-ac4f6f229257' User entered '98.2'	System	11 Aug 2020 22:53:28
	System	11 Aug 2020 22:53:28

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:53:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '045c0790-9062-4dde-9f17-ac4f6f229257'	System	11 Aug 2020 22:53:28
User entered 'No (N)'	System	11 Aug 2020 22:53:28

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:53:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '045c0790-9062-4dde-9f17-ac4f6f229257'	System	11 Aug 2020 22:53:28
User entered '11 Aug 2020 17:53'	System	11 Aug 2020 22:53:28

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 17:34'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 20:04'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:30:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '41d5bb43-5770-45cc-a52c-2cf6a1fc2670' User entered 'Yes (Y)'	System	12 Aug 2020 02:30:54
	System	12 Aug 2020 02:30:54

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:30:39', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '41d5bb43-5770-45cc-a52c-2cf6a1fc2670' User entered '97.7'	System	12 Aug 2020 02:30:54
	System	12 Aug 2020 02:30:54

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:30:43', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '41d5bb43-5770-45cc-a52c-2cf6a1fc2670' User entered 'No (N)'	System	12 Aug 2020 02:30:54
	System	12 Aug 2020 02:30:54

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:30:51', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '41d5bb43-5770-45cc-a52c-2cf6a1fc2670' User entered '11 Aug 2020 21:30'	System	12 Aug 2020 02:30:54
	System	12 Aug 2020 02:30:54

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 20:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 2'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:31:52', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e4585727-e6c2-4352-b00e-b085e2d6ada9' User entered 'Yes (Y)'	System	12 Aug 2020 18:32:19
	System	12 Aug 2020 18:32:19

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:32:01', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e4585727-e6c2-4352-b00e-b085e2d6ada9' User entered '96.7'	System	12 Aug 2020 18:32:19
	System	12 Aug 2020 18:32:19

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:32:08', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e4585727-e6c2-4352-b00e-b085e2d6ada9' User entered 'No (N)'	System	12 Aug 2020 18:32:19
	System	12 Aug 2020 18:32:19

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:32:17', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e4585727-e6c2-4352-b00e-b085e2d6ada9' User entered '12 Aug 2020 13:32'	System	12 Aug 2020 18:32:19
	System	12 Aug 2020 18:32:19

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 3'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:36:35', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'eb2ec2e0-eb9f-4878-b99a-9b55ec7c3cfc' User entered 'Yes (Y)'	System	13 Aug 2020 17:36:57
	System	13 Aug 2020 17:36:57

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:36:41', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'eb2ec2e0-eb9f-4878-b99a-9b55ec7c3cfc' User entered '96.6'	System	13 Aug 2020 17:36:57
	System	13 Aug 2020 17:36:57

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:36:46', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'eb2ec2e0-eb9f-4878-b99a-9b55ec7c3cfc' User entered 'No (N)'	System	13 Aug 2020 17:36:57
	System	13 Aug 2020 17:36:57

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:36:53', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'eb2ec2e0-eb9f-4878-b99a-9b55ec7c3cfc' User entered '13 Aug 2020 12:36'	System	13 Aug 2020 17:36:57
	System	13 Aug 2020 17:36:57

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 4'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:53:30', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '77c8d011-b145-440d-bed9-e643c5a83aec' User entered 'Yes (Y)'	System	14 Aug 2020 22:53:49
	System	14 Aug 2020 22:53:49

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:53:36', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '77c8d011-b145-440d-bed9-e643c5a83aec' User entered '97.6'	System	14 Aug 2020 22:53:49
	System	14 Aug 2020 22:53:49

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:53:42', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '77c8d011-b145-440d-bed9-e643c5a83aec' User entered 'No (N)'	System	14 Aug 2020 22:53:49
	System	14 Aug 2020 22:53:49

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:53:46', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '77c8d011-b145-440d-bed9-e643c5a83aec' User entered '14 Aug 2020 17:53'	System	14 Aug 2020 22:53:49
	System	14 Aug 2020 22:53:49

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 5'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:38:30', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '4ec719c8-103d-4ae8-a7d5-183955454d5d' User entered 'Yes (Y)'	System	16 Aug 2020 00:38:52
	System	16 Aug 2020 00:38:52

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:38:41', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '4ec719c8-103d-4ae8-a7d5-183955454d5d' User entered '97.9'	System	16 Aug 2020 00:38:52
	System	16 Aug 2020 00:38:52

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:38:47', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '4ec719c8-103d-4ae8-a7d5-183955454d5d' User entered 'No (N)'	System	16 Aug 2020 00:38:52
	System	16 Aug 2020 00:38:52

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:38:50', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '4ec719c8-103d-4ae8-a7d5-183955454d5d' User entered '15 Aug 2020 19:38'	System	16 Aug 2020 00:38:52
	System	16 Aug 2020 00:38:52

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 6'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:44:53', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '681546d8-e7e5-4175-8475-e16d4a2c5d0f' User entered 'Yes (Y)'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:44:59', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '681546d8-e7e5-4175-8475-e16d4a2c5d0f' User entered '96.8'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:05', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '681546d8-e7e5-4175-8475-e16d4a2c5d0f' User entered 'No (N)'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '681546d8-e7e5-4175-8475-e16d4a2c5d0f' User entered '16 Aug 2020 14:45'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 7'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:42:58', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '241ea528-21ae-4a82-b07d-dfd61fe8b43e' User entered 'Yes (Y)'	System	17 Aug 2020 17:43:17
	System	17 Aug 2020 17:43:17

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:05', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '241ea528-21ae-4a82-b07d-dfd61fe8b43e' User entered '97.2'	System	17 Aug 2020 17:43:17
	System	17 Aug 2020 17:43:17

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:10', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '241ea528-21ae-4a82-b07d-dfd61fe8b43e' User entered 'No (N)'	System	17 Aug 2020 17:43:17
	System	17 Aug 2020 17:43:17

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:14', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '241ea528-21ae-4a82-b07d-dfd61fe8b43e' User entered '17 Aug 2020 12:43'	System	17 Aug 2020 17:43:17
	System	17 Aug 2020 17:43:17

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:53:51', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '896b8217-5a5f-4ef2-b539-bec0643be55f' User entered 'None (1)'	System	11 Aug 2020 22:54:23
	System	11 Aug 2020 22:54:23

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:53:56', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '896b8217-5a5f-4ef2-b539-bec0643be55f' User entered 'No (N)'	System	11 Aug 2020 22:54:23
	System	11 Aug 2020 22:54:23

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:54:03', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '896b8217-5a5f-4ef2-b539-bec0643be55f' User entered 'No (N)'	System	11 Aug 2020 22:54:23
	System	11 Aug 2020 22:54:23

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:54:17', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '896b8217-5a5f-4ef2-b539-bec0643be55f' User entered 'None (1)'	System	11 Aug 2020 22:54:23
	System	11 Aug 2020 22:54:23

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:54:21', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '896b8217-5a5f-4ef2-b539-bec0643be55f' User entered '11 Aug 2020 17:54'	System	11 Aug 2020 22:54:23
	System	11 Aug 2020 22:54:23

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 17:34'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 20:04'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:13', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '7e3dd9b3-c4f5-47d9-bf7c-a2c8d7556ea1' User entered 'None (1)'	System	12 Aug 2020 02:31:33
	System	12 Aug 2020 02:31:33

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:17', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '7e3dd9b3-c4f5-47d9-bf7c-a2c8d7556ea1' User entered 'No (N)'	System	12 Aug 2020 02:31:33
	System	12 Aug 2020 02:31:33

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:23', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '7e3dd9b3-c4f5-47d9-bf7c-a2c8d7556ea1' User entered 'No (N)'	System	12 Aug 2020 02:31:33
	System	12 Aug 2020 02:31:33

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:27', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '7e3dd9b3-c4f5-47d9-bf7c-a2c8d7556ea1' User entered 'None (1)'	System	12 Aug 2020 02:31:33
	System	12 Aug 2020 02:31:33

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '7e3dd9b3-c4f5-47d9-bf7c-a2c8d7556ea1' User entered '11 Aug 2020 21:31'	System	12 Aug 2020 02:31:33
	System	12 Aug 2020 02:31:33

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 20:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 2'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:32:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '352b9ed0-b852-44e3-893b-c8176aabad6e' User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 18:36:49
	System	12 Aug 2020 18:36:49

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:32:36', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '352b9ed0-b852-44e3-893b-c8176aabad6e' User entered 'No (N)'	System	12 Aug 2020 18:36:49
	System	12 Aug 2020 18:36:49

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:32:42', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '352b9ed0-b852-44e3-893b-c8176aabad6e' User entered 'Yes (Y)'	System	12 Aug 2020 18:36:49
	System	12 Aug 2020 18:36:49

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:36:14', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '352b9ed0-b852-44e3-893b-c8176aabad6e' User entered '30'	System	12 Aug 2020 18:36:49
	System	12 Aug 2020 18:36:49

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:33:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '352b9ed0-b852-44e3-893b-c8176aabad6e' User entered 'None (1)'	System	12 Aug 2020 18:36:49
	System	12 Aug 2020 18:36:49

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:36:44', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '352b9ed0-b852-44e3-893b-c8176aabad6e' User entered '12 Aug 2020 13:36'	System	12 Aug 2020 18:36:49
	System	12 Aug 2020 18:36:49

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 3'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:02', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '81e28fae-f88d-4668-a769-a5d5aaa9cede'	System	13 Aug 2020 17:37:30
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 17:37:30

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '81e28fae-f88d-4668-a769-a5d5aaa9cede' User entered 'No (N)'	System	13 Aug 2020 17:37:30
	System	13 Aug 2020 17:37:30

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:13', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '81e28fae-f88d-4668-a769-a5d5aaa9cede' User entered 'Yes (Y)'	System	13 Aug 2020 17:37:30
	System	13 Aug 2020 17:37:30

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '81e28fae-f88d-4668-a769-a5d5aaa9cede' User entered '10'	System	13 Aug 2020 17:37:30
	System	13 Aug 2020 17:37:30

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '81e28fae-f88d-4668-a769-a5d5aaa9cede' User entered 'None (1)'	System	13 Aug 2020 17:37:30
	System	13 Aug 2020 17:37:30

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:28', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '81e28fae-f88d-4668-a769-a5d5aaa9cede' User entered '13 Aug 2020 12:37'	System	13 Aug 2020 17:37:30
	System	13 Aug 2020 17:37:30

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 4'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:54:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '92006ac1-1347-4c5c-a00c-2506616b1775' User entered 'None (1)'	System	14 Aug 2020 22:54:24
	System	14 Aug 2020 22:54:24

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:54:04', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '92006ac1-1347-4c5c-a00c-2506616b1775' User entered 'No (N)'	System	14 Aug 2020 22:54:24
	System	14 Aug 2020 22:54:24

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:54:08', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '92006ac1-1347-4c5c-a00c-2506616b1775' User entered 'No (N)'	System	14 Aug 2020 22:54:24
	System	14 Aug 2020 22:54:24

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:54:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '92006ac1-1347-4c5c-a00c-2506616b1775'	System	14 Aug 2020 22:54:24
User entered 'None (1)'	System	14 Aug 2020 22:54:24

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:54:23', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '92006ac1-1347-4c5c-a00c-2506616b1775' User entered '14 Aug 2020 17:54'	System	14 Aug 2020 22:54:24
	System	14 Aug 2020 22:54:24

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 5'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:38:55', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a67720d1-7ed8-447b-8ca7-e6cbd35aaa4a' User entered 'None (1)'	System	16 Aug 2020 00:39:16
	System	16 Aug 2020 00:39:16

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:38:59', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a67720d1-7ed8-447b-8ca7-e6cbd35aaa4a' User entered 'No (N)'	System	16 Aug 2020 00:39:16
	System	16 Aug 2020 00:39:16

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:03', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a67720d1-7ed8-447b-8ca7-e6cbd35aaa4a' User entered 'No (N)'	System	16 Aug 2020 00:39:16
	System	16 Aug 2020 00:39:16

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a67720d1-7ed8-447b-8ca7-e6cbd35aaa4a' User entered 'None (1)'	System	16 Aug 2020 00:39:16
	System	16 Aug 2020 00:39:16

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:13', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a67720d1-7ed8-447b-8ca7-e6cbd35aaa4a' User entered '15 Aug 2020 19:39'	System	16 Aug 2020 00:39:16
	System	16 Aug 2020 00:39:16

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 6'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:20', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf343d3f-9985-467d-8ee5-5960589c4a2b' User entered 'None (1)'	System	16 Aug 2020 19:45:38
	System	16 Aug 2020 19:45:38

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf343d3f-9985-467d-8ee5-5960589c4a2b' User entered 'No (N)'	System	16 Aug 2020 19:45:38
	System	16 Aug 2020 19:45:38

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:26', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf343d3f-9985-467d-8ee5-5960589c4a2b' User entered 'No (N)'	System	16 Aug 2020 19:45:38
	System	16 Aug 2020 19:45:38

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:29', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf343d3f-9985-467d-8ee5-5960589c4a2b' User entered 'None (1)'	System	16 Aug 2020 19:45:38
	System	16 Aug 2020 19:45:38

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:36', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf343d3f-9985-467d-8ee5-5960589c4a2b' User entered '16 Aug 2020 14:45'	System	16 Aug 2020 19:45:38
	System	16 Aug 2020 19:45:38

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 7'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '019fb438-9425-4a97-8bb1-ab7732c8d153'	System	17 Aug 2020 17:43:36
User entered 'None (1)'	System	17 Aug 2020 17:43:36

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:23', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '019fb438-9425-4a97-8bb1-ab7732c8d153' User entered 'No (N)'	System	17 Aug 2020 17:43:36
	System	17 Aug 2020 17:43:36

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:27', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '019fb438-9425-4a97-8bb1-ab7732c8d153'	System	17 Aug 2020 17:43:36
User entered 'No (N)'	System	17 Aug 2020 17:43:36

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '019fb438-9425-4a97-8bb1-ab7732c8d153'	System	17 Aug 2020 17:43:36
User entered 'None (1)'	System	17 Aug 2020 17:43:36

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:34', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '019fb438-9425-4a97-8bb1-ab7732c8d153'	System	17 Aug 2020 17:43:36
User entered '17 Aug 2020 12:43'	System	17 Aug 2020 17:43:36

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:54:40', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '994a1a05-4e34-4b5c-bb70-8a74019a86d1' User entered 'None (0)'	System	11 Aug 2020 22:55:13
	System	11 Aug 2020 22:55:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:54:43', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '994a1a05-4e34-4b5c-bb70-8a74019a86d1' User entered 'None (0)'	System	11 Aug 2020 22:55:13
	System	11 Aug 2020 22:55:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:54:47', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '994a1a05-4e34-4b5c-bb70-8a74019a86d1' User entered 'None (0)'	System	11 Aug 2020 22:55:13
	System	11 Aug 2020 22:55:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:54:55', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '994a1a05-4e34-4b5c-bb70-8a74019a86d1' User entered 'None (0)'	System	11 Aug 2020 22:55:13
	System	11 Aug 2020 22:55:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:54:58', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '994a1a05-4e34-4b5c-bb70-8a74019a86d1' User entered 'None (0)'	System	11 Aug 2020 22:55:13
	System	11 Aug 2020 22:55:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:55:01', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '994a1a05-4e34-4b5c-bb70-8a74019a86d1' User entered 'None (0)'	System	11 Aug 2020 22:55:13
	System	11 Aug 2020 22:55:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:55:08', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '994a1a05-4e34-4b5c-bb70-8a74019a86d1' User entered 'No (N)'	System	11 Aug 2020 22:55:13
	System	11 Aug 2020 22:55:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T17:55:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '994a1a05-4e34-4b5c-bb70-8a74019a86d1' User entered '11 Aug 2020 17:55'	System	11 Aug 2020 22:55:13
	System	11 Aug 2020 22:55:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 17:34'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 20:04'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:43', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bdf794bb-2b6e-4f70-8fec-3213d17ff82b' User entered 'None (0)'	System	12 Aug 2020 02:32:07
	System	12 Aug 2020 02:32:07

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:46', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bdf794bb-2b6e-4f70-8fec-3213d17ff82b' User entered 'None (0)'	System	12 Aug 2020 02:32:07
	System	12 Aug 2020 02:32:07

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:50', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bdf794bb-2b6e-4f70-8fec-3213d17ff82b' User entered 'None (0)'	System	12 Aug 2020 02:32:07
	System	12 Aug 2020 02:32:07

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:53', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bdf794bb-2b6e-4f70-8fec-3213d17ff82b' User entered 'None (0)'	System	12 Aug 2020 02:32:07
	System	12 Aug 2020 02:32:07

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:56', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bdf794bb-2b6e-4f70-8fec-3213d17ff82b' User entered 'None (0)'	System	12 Aug 2020 02:32:07
	System	12 Aug 2020 02:32:07

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:31:59', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bdf794bb-2b6e-4f70-8fec-3213d17ff82b' User entered 'None (0)'	System	12 Aug 2020 02:32:07
	System	12 Aug 2020 02:32:07

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:32:02', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bdf794bb-2b6e-4f70-8fec-3213d17ff82b' User entered 'No (N)'	System	12 Aug 2020 02:32:07
	System	12 Aug 2020 02:32:07

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-11T21:32:06', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bdf794bb-2b6e-4f70-8fec-3213d17ff82b' User entered '11 Aug 2020 21:32'	System	12 Aug 2020 02:32:07
	System	12 Aug 2020 02:32:07

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Aug 2020 20:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 2'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:36:55', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'aa7e9df9-f7e0-46c8-9d70-36b3710e8fa1' User entered 'None (0)'	System	12 Aug 2020 18:37:31
	System	12 Aug 2020 18:37:31

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:36:59', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'aa7e9df9-f7e0-46c8-9d70-36b3710e8fa1' User entered 'None (0)'	System	12 Aug 2020 18:37:31
	System	12 Aug 2020 18:37:31

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:37:04', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'aa7e9df9-f7e0-46c8-9d70-36b3710e8fa1' User entered 'None (0)'	System	12 Aug 2020 18:37:31
	System	12 Aug 2020 18:37:31

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:37:08', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'aa7e9df9-f7e0-46c8-9d70-36b3710e8fa1' User entered 'None (0)'	System	12 Aug 2020 18:37:31
	System	12 Aug 2020 18:37:31

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:37:11', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'aa7e9df9-f7e0-46c8-9d70-36b3710e8fa1' User entered 'None (0)'	System	12 Aug 2020 18:37:31
	System	12 Aug 2020 18:37:31

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:37:14', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'aa7e9df9-f7e0-46c8-9d70-36b3710e8fa1' User entered 'None (0)'	System	12 Aug 2020 18:37:31
	System	12 Aug 2020 18:37:31

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:37:18', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'aa7e9df9-f7e0-46c8-9d70-36b3710e8fa1' User entered 'No (N)'	System	12 Aug 2020 18:37:31
	System	12 Aug 2020 18:37:31

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-12T13:37:29', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'aa7e9df9-f7e0-46c8-9d70-36b3710e8fa1' User entered '12 Aug 2020 13:37'	System	12 Aug 2020 18:37:31
	System	12 Aug 2020 18:37:31

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 3'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:34', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9edc4c5a-063d-4cac-8563-5516dc0a45f4' User entered 'None (0)'	System	13 Aug 2020 17:38:08
	System	13 Aug 2020 17:38:08

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:38', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9edc4c5a-063d-4cac-8563-5516dc0a45f4' User entered 'None (0)'	System	13 Aug 2020 17:38:08
	System	13 Aug 2020 17:38:08

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:48', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9edc4c5a-063d-4cac-8563-5516dc0a45f4' User entered 'None (0)'	System	13 Aug 2020 17:38:08
	System	13 Aug 2020 17:38:08

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:52', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9edc4c5a-063d-4cac-8563-5516dc0a45f4' User entered 'None (0)'	System	13 Aug 2020 17:38:08
	System	13 Aug 2020 17:38:08

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:55', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9edc4c5a-063d-4cac-8563-5516dc0a45f4' User entered 'None (0)'	System	13 Aug 2020 17:38:08
	System	13 Aug 2020 17:38:08

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:37:57', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9edc4c5a-063d-4cac-8563-5516dc0a45f4' User entered 'None (0)'	System	13 Aug 2020 17:38:08
	System	13 Aug 2020 17:38:08

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:38:01', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9edc4c5a-063d-4cac-8563-5516dc0a45f4' User entered 'No (N)'	System	13 Aug 2020 17:38:08
	System	13 Aug 2020 17:38:08

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-13T12:38:04', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9edc4c5a-063d-4cac-8563-5516dc0a45f4' User entered '13 Aug 2020 12:38'	System	13 Aug 2020 17:38:08
	System	13 Aug 2020 17:38:08

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 4'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:55:04', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6cfca47a-5eee-47a1-ace2-52c99c0c42e3' User entered 'None (0)'	System	14 Aug 2020 22:55:34
	System	14 Aug 2020 22:55:34

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:55:09', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6cfca47a-5eee-47a1-ace2-52c99c0c42e3' User entered 'None (0)'	System	14 Aug 2020 22:55:34
	System	14 Aug 2020 22:55:34

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:55:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6cfca47a-5eee-47a1-ace2-52c99c0c42e3' User entered 'None (0)'	System	14 Aug 2020 22:55:34
	System	14 Aug 2020 22:55:34

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:55:16', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6cfca47a-5eee-47a1-ace2-52c99c0c42e3' User entered 'None (0)'	System	14 Aug 2020 22:55:34
	System	14 Aug 2020 22:55:34

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:55:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6cfca47a-5eee-47a1-ace2-52c99c0c42e3' User entered 'None (0)'	System	14 Aug 2020 22:55:34
	System	14 Aug 2020 22:55:34

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:55:22', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6cfca47a-5eee-47a1-ace2-52c99c0c42e3' User entered 'None (0)'	System	14 Aug 2020 22:55:34
	System	14 Aug 2020 22:55:34

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:55:26', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6cfca47a-5eee-47a1-ace2-52c99c0c42e3' User entered 'No (N)'	System	14 Aug 2020 22:55:34
	System	14 Aug 2020 22:55:34

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-14T17:55:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6cfca47a-5eee-47a1-ace2-52c99c0c42e3' User entered '14 Aug 2020 17:55'	System	14 Aug 2020 22:55:34
	System	14 Aug 2020 22:55:34

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 5'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:18', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '33131002-ed0b-4854-a5cf-e39a0a46bb50' User entered 'None (0)'	System	16 Aug 2020 00:39:42
	System	16 Aug 2020 00:39:42

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:20', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '33131002-ed0b-4854-a5cf-e39a0a46bb50' User entered 'None (0)'	System	16 Aug 2020 00:39:42
	System	16 Aug 2020 00:39:42

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:23', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '33131002-ed0b-4854-a5cf-e39a0a46bb50' User entered 'None (0)'	System	16 Aug 2020 00:39:42
	System	16 Aug 2020 00:39:42

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:26', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '33131002-ed0b-4854-a5cf-e39a0a46bb50' User entered 'None (0)'	System	16 Aug 2020 00:39:42
	System	16 Aug 2020 00:39:42

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:29', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '33131002-ed0b-4854-a5cf-e39a0a46bb50' User entered 'None (0)'	System	16 Aug 2020 00:39:42
	System	16 Aug 2020 00:39:42

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:32', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '33131002-ed0b-4854-a5cf-e39a0a46bb50' User entered 'None (0)'	System	16 Aug 2020 00:39:42
	System	16 Aug 2020 00:39:42

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:36', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '33131002-ed0b-4854-a5cf-e39a0a46bb50' User entered 'No (N)'	System	16 Aug 2020 00:39:42
	System	16 Aug 2020 00:39:42

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-15T19:39:39', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '33131002-ed0b-4854-a5cf-e39a0a46bb50' User entered '15 Aug 2020 19:39'	System	16 Aug 2020 00:39:42
	System	16 Aug 2020 00:39:42

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 6'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:41', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c87ef1e6-4611-48e3-b3da-c98d35be5b15' User entered 'None (0)'	System	16 Aug 2020 19:46:04
	System	16 Aug 2020 19:46:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:44', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c87ef1e6-4611-48e3-b3da-c98d35be5b15' User entered 'None (0)'	System	16 Aug 2020 19:46:04
	System	16 Aug 2020 19:46:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:46', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c87ef1e6-4611-48e3-b3da-c98d35be5b15' User entered 'None (0)'	System	16 Aug 2020 19:46:04
	System	16 Aug 2020 19:46:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:49', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c87ef1e6-4611-48e3-b3da-c98d35be5b15' User entered 'None (0)'	System	16 Aug 2020 19:46:04
	System	16 Aug 2020 19:46:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:52', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c87ef1e6-4611-48e3-b3da-c98d35be5b15' User entered 'None (0)'	System	16 Aug 2020 19:46:04
	System	16 Aug 2020 19:46:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:54', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c87ef1e6-4611-48e3-b3da-c98d35be5b15' User entered 'None (0)'	System	16 Aug 2020 19:46:04
	System	16 Aug 2020 19:46:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:45:59', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c87ef1e6-4611-48e3-b3da-c98d35be5b15' User entered 'No (N)'	System	16 Aug 2020 19:46:04
	System	16 Aug 2020 19:46:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-16T14:46:02', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c87ef1e6-4611-48e3-b3da-c98d35be5b15' User entered '16 Aug 2020 14:46'	System	16 Aug 2020 19:46:04
	System	16 Aug 2020 19:46:04

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 7'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:38', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'cf51e92a-170c-4ab0-bc58-773ae7b9bec5' User entered 'None (0)'	System	17 Aug 2020 17:44:02
	System	17 Aug 2020 17:44:02

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:41', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'cf51e92a-170c-4ab0-bc58-773ae7b9bec5' User entered 'None (0)'	System	17 Aug 2020 17:44:02
	System	17 Aug 2020 17:44:02

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:43', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'cf51e92a-170c-4ab0-bc58-773ae7b9bec5' User entered 'None (0)'	System	17 Aug 2020 17:44:02
	System	17 Aug 2020 17:44:02

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:46', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'cf51e92a-170c-4ab0-bc58-773ae7b9bec5' User entered 'None (0)'	System	17 Aug 2020 17:44:02
	System	17 Aug 2020 17:44:02

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:49', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'cf51e92a-170c-4ab0-bc58-773ae7b9bec5' User entered 'None (0)'	System	17 Aug 2020 17:44:02
	System	17 Aug 2020 17:44:02

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:51', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'cf51e92a-170c-4ab0-bc58-773ae7b9bec5' User entered 'None (0)'	System	17 Aug 2020 17:44:02
	System	17 Aug 2020 17:44:02

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:56', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'cf51e92a-170c-4ab0-bc58-773ae7b9bec5' User entered 'No (N)'	System	17 Aug 2020 17:44:02
	System	17 Aug 2020 17:44:02

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-08-17T12:43:59', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'cf51e92a-170c-4ab0-bc58-773ae7b9bec5' User entered '17 Aug 2020 12:43'	System	17 Aug 2020 17:44:02
	System	17 Aug 2020 17:44:02

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:32:13

US3812132

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:58:05
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:43:15

US3812132

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:58:05
User entered '18 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:43:15

US3812132

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:58:05
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:43:15

US3812132

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:58:05
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:43:15

US3812132

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:58:28
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	27 Aug 2020 17:44:19

US3812132

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered '1'	System	27 Aug 2020 17:44:19

US3812132

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:59:01
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	27 Aug 2020 17:44:36

US3812132

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:59:01
User entered '26 Aug 2020'	Angie Kean (b) (4) (b) (4)	27 Aug 2020 17:44:36

US3812132

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:59:01
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4) (b) (4)	27 Aug 2020 17:44:36

US3812132

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:59:01
User entered empty.	Angie Kean (b) (4) (b) (4)	27 Aug 2020 17:44:36

US3812132

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:02:56
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 14:53:31

US3812132

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:12:18
User entered '1'	System	03 Sep 2020 14:53:31

US3812132

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:03:38
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	03 Sep 2020 19:56:00

US3812132

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:03:38
User entered '1 Sep 2020'	Angie Kean (b) (4) (b) (4)	03 Sep 2020 19:56:00

US3812132

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:03:38
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4) (b) (4)	03 Sep 2020 19:56:00

US3812132

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:03:38
User entered empty.	Angie Kean (b) (4) (b) (4)	03 Sep 2020 19:56:00

US3812132

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:03:50
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	08 Sep 2020 18:25:35

US3812132

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:32
User entered '1'	System	08 Sep 2020 18:25:35

US3812132

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:00
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	08 Sep 2020 18:26:50

US3812132

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:00
User entered '8 Sep 2020'	Heather Cherniawski (b) (4)	08 Sep 2020 18:26:50

US3812132

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:00
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	08 Sep 2020 18:26:50

US3812132

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'VISIT2'	System	08 Sep 2020 18:26:50

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '8 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '12:33'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered '8 Sep 2020 12:33'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '98.0' F	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '82'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'bpm'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '18'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'breaths/min'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '124'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'mmHg'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '78'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'mmHg'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '8 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '13:29'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered '8 Sep 2020 13:29'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
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)	07 Oct 2020 10:58:29
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Anya Penly (b) (4) (b) (4)	02 Oct 2020 19:40:10
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 23:52:45
User entered '96.5' F	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '80'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'bpm'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '12'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'breaths/min'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '138'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'mmHg'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:05:34
User entered '90'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'mmHg'	System	11 Sep 2020 18:07:03

US3812132

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Sep 2020 18:05:31

US3812132

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:05:31

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:02
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:02
User entered empty.	Heather Cherniawski (b) (4)	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

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 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:02
User entered empty.	Heather Cherniawski (b) (4)	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:02
User entered '8 Sep 2020'	Heather Cherniawski (b) (4)	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:02
User entered '12:58'	Heather Cherniawski (b) (4)	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered '8 Sep 2020 12:58'	System	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:02
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski (b) (4)	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:06:02
User entered 'ONCE'	System	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:14

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:27:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:07:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:05:54

US3812132

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:07:13
User entered '8 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:05:54

US3812132

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:07:13
User entered '12:45'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:05:54

US3812132

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered '8 Sep 2020 12:45'	System	11 Sep 2020 18:05:54

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:50:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:47
User entered '8 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:47
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:47
User entered '12:48'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User entered '8 Sep 2020 12:48'	System	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:47
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:47
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User entered empty.	System	11 Sep 2020 18:06:09

US3812132

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:06:20
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	13 Sep 2020 13:39:52

US3812132

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User entered '1'	System	13 Sep 2020 13:39:52

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c56c635-c853-430f-97b6-5d687508fd93' User entered 'Yes (Y)'	System	08 Sep 2020 18:39:20
	System	08 Sep 2020 18:39:20

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:09', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c56c635-c853-430f-97b6-5d687508fd93' User entered '96.5'	System	08 Sep 2020 18:39:20
	System	08 Sep 2020 18:39:20

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c56c635-c853-430f-97b6-5d687508fd93' User entered 'No (N)'	System	08 Sep 2020 18:39:20
	System	08 Sep 2020 18:39:20

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:16', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c56c635-c853-430f-97b6-5d687508fd93'	System	08 Sep 2020 18:39:20
User entered '08 Sep 2020 13:39'	System	08 Sep 2020 18:39:20

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 13:18'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 15:48'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:08:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '619ff9b6-d4f2-41e4-815f-9ce0118d7653' User entered 'Yes (Y)'	System	09 Sep 2020 02:08:45
	System	09 Sep 2020 02:08:45

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:08:32', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '619ff9b6-d4f2-41e4-815f-9ce0118d7653' User entered '97.9'	System	09 Sep 2020 02:08:45
	System	09 Sep 2020 02:08:45

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:08:37', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '619ff9b6-d4f2-41e4-815f-9ce0118d7653'	System	09 Sep 2020 02:08:45
User entered 'No (N)'	System	09 Sep 2020 02:08:45

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:08:43', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '619ff9b6-d4f2-41e4-815f-9ce0118d7653'	System	09 Sep 2020 02:08:45
User entered '08 Sep 2020 21:08'	System	09 Sep 2020 02:08:45

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 16:43'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 2'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:25:26', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ef180985-775f-43dc-b1ce-903b704aaa0d' User entered 'Yes (Y)'	System	09 Sep 2020 17:25:57
	System	09 Sep 2020 17:25:57

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:25:33', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ef180985-775f-43dc-b1ce-903b704aaa0d' User entered '98.3'	System	09 Sep 2020 17:25:57
	System	09 Sep 2020 17:25:57

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:25:38', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ef180985-775f-43dc-b1ce-903b704aaa0d' User entered 'Yes (Y)'	System	09 Sep 2020 17:25:57
	System	09 Sep 2020 17:25:57

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 11:22:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:25:48', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ef180985-775f-43dc-b1ce-903b704aaa0d' User entered '1'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 21:15:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Sep 2020 17:25:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:25:48', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ef180985-775f-43dc-b1ce-903b704aaa0d' User entered '1'	System	09 Sep 2020 17:25:57
User entered '1'	System	09 Sep 2020 17:25:57

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:25:48', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ef180985-775f-43dc-b1ce-903b704aaa0d' User entered '0'	System	09 Sep 2020 17:25:57
	System	09 Sep 2020 17:25:57

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:25:55', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ef180985-775f-43dc-b1ce-903b704aaa0d' User entered '09 Sep 2020 12:25'	System	09 Sep 2020 17:25:57
	System	09 Sep 2020 17:25:57

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 3'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:26:52', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3ad5fc38-17cc-4e1d-b5b9-9731d917d60f' User entered 'Yes (Y)'	System	10 Sep 2020 19:27:22
	System	10 Sep 2020 19:27:22

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:26:58', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3ad5fc38-17cc-4e1d-b5b9-9731d917d60f' User entered '97.3'	System	10 Sep 2020 19:27:22
	System	10 Sep 2020 19:27:22

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:04', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3ad5fc38-17cc-4e1d-b5b9-9731d917d60f' User entered 'Yes (Y)'	System	10 Sep 2020 19:27:22
	System	10 Sep 2020 19:27:22

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 11:22:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3ad5fc38-17cc-4e1d-b5b9-9731d917d60f' User entered '1'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 21:15:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Sep 2020 19:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3ad5fc38-17cc-4e1d-b5b9-9731d917d60f' User entered '1'	System	10 Sep 2020 19:27:22
User entered '1'	System	10 Sep 2020 19:27:22

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3ad5fc38-17cc-4e1d-b5b9-9731d917d60f' User entered '0'	System	10 Sep 2020 19:27:22
	System	10 Sep 2020 19:27:22

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:21', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3ad5fc38-17cc-4e1d-b5b9-9731d917d60f' User entered '10 Sep 2020 14:27'	System	10 Sep 2020 19:27:22
	System	10 Sep 2020 19:27:22

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 4'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:18:26', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a59c1b7c-3122-4a5b-b9dd-4d7d4e44a947' User entered 'Yes (Y)'	System	11 Sep 2020 19:18:53
	System	11 Sep 2020 19:18:53

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:18:34', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a59c1b7c-3122-4a5b-b9dd-4d7d4e44a947' User entered '96.5'	System	11 Sep 2020 19:18:53
	System	11 Sep 2020 19:18:53

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:18:42', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a59c1b7c-3122-4a5b-b9dd-4d7d4e44a947'	System	11 Sep 2020 19:18:53
User entered 'No (N)'	System	11 Sep 2020 19:18:53

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:18:52', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a59c1b7c-3122-4a5b-b9dd-4d7d4e44a947'	System	11 Sep 2020 19:18:53
User entered '11 Sep 2020 14:18'	System	11 Sep 2020 19:18:53

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 5'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:00:30', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b1bcee1-8291-4fe8-a575-6c5de6965c50' User entered 'Yes (Y)'	System	12 Sep 2020 17:01:27
	System	12 Sep 2020 17:01:27

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:00:39', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b1bcee1-8291-4fe8-a575-6c5de6965c50' User entered '97.9'	System	12 Sep 2020 17:01:27
	System	12 Sep 2020 17:01:27

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:00:51', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b1bcee1-8291-4fe8-a575-6c5de6965c50' User entered 'No (N)'	System	12 Sep 2020 17:01:27
	System	12 Sep 2020 17:01:27

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:00:56', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b1bcee1-8291-4fe8-a575-6c5de6965c50' User entered '12 Sep 2020 12:00'	System	12 Sep 2020 17:01:27
	System	12 Sep 2020 17:01:27

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 6'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:45:57', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '93144c64-37c8-4da6-9f17-15503c2fb6ad' User entered 'Yes (Y)'	System	13 Sep 2020 20:46:36
	System	13 Sep 2020 20:46:36

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:46:03', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '93144c64-37c8-4da6-9f17-15503c2fb6ad' User entered '96.5'	System	13 Sep 2020 20:46:36
	System	13 Sep 2020 20:46:36

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:46:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '93144c64-37c8-4da6-9f17-15503c2fb6ad' User entered 'No (N)'	System	13 Sep 2020 20:46:36
	System	13 Sep 2020 20:46:36

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:46:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '93144c64-37c8-4da6-9f17-15503c2fb6ad' User entered '13 Sep 2020 15:46'	System	13 Sep 2020 20:46:36
	System	13 Sep 2020 20:46:36

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 7'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:48:20', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '250b2409-7337-4f52-bafc-89e6d8ba75af' User entered 'Yes (Y)'	System	14 Sep 2020 19:48:36
	System	14 Sep 2020 19:48:36

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:48:26', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '250b2409-7337-4f52-bafc-89e6d8ba75af' User entered '97.1'	System	14 Sep 2020 19:48:36
	System	14 Sep 2020 19:48:36

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:48:30', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '250b2409-7337-4f52-bafc-89e6d8ba75af' User entered 'No (N)'	System	14 Sep 2020 19:48:36
	System	14 Sep 2020 19:48:36

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:48:34', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '250b2409-7337-4f52-bafc-89e6d8ba75af' User entered '14 Sep 2020 14:48'	System	14 Sep 2020 19:48:36
	System	14 Sep 2020 19:48:36

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9df63f71-69da-4808-b37b-cbbff1cf7033'	System	08 Sep 2020 18:39:54
User entered 'None (1)'	System	08 Sep 2020 18:39:54

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:38', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9df63f71-69da-4808-b37b-cbbff1cf7033' User entered 'No (N)'	System	08 Sep 2020 18:39:54
	System	08 Sep 2020 18:39:54

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:43', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9df63f71-69da-4808-b37b-cbbff1cf7033' User entered 'No (N)'	System	08 Sep 2020 18:39:54
	System	08 Sep 2020 18:39:54

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:46', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9df63f71-69da-4808-b37b-cbbff1cf7033'	System	08 Sep 2020 18:39:54
User entered 'None (1)'	System	08 Sep 2020 18:39:54

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:50', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9df63f71-69da-4808-b37b-cbbff1cf7033' User entered '08 Sep 2020 13:39'	System	08 Sep 2020 18:39:54
	System	08 Sep 2020 18:39:54

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 13:18'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 15:48'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:10:02', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '25d3bb8f-4141-4db7-8b18-6c1bd0de4fdf' User entered 'None (1)'	System	09 Sep 2020 02:10:35
	System	09 Sep 2020 02:10:35

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:10:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '25d3bb8f-4141-4db7-8b18-6c1bd0de4fdf' User entered 'No (N)'	System	09 Sep 2020 02:10:35
	System	09 Sep 2020 02:10:35

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:10:11', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '25d3bb8f-4141-4db7-8b18-6c1bd0de4fdf' User entered 'No (N)'	System	09 Sep 2020 02:10:35
	System	09 Sep 2020 02:10:35

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:10:27', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '25d3bb8f-4141-4db7-8b18-6c1bd0de4fdf' User entered 'None (1)'	System	09 Sep 2020 02:10:35
	System	09 Sep 2020 02:10:35

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:10:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '25d3bb8f-4141-4db7-8b18-6c1bd0de4fdf' User entered '08 Sep 2020 21:10'	System	09 Sep 2020 02:10:35
	System	09 Sep 2020 02:10:35

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 16:43'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 2'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:26:05', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '67c787d4-9f62-4acf-80e2-a5152adf7298'	System	09 Sep 2020 17:26:56
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 17:26:56

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:26:10', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '67c787d4-9f62-4acf-80e2-a5152adf7298'	System	09 Sep 2020 17:26:56
User entered 'No (N)'	System	09 Sep 2020 17:26:56

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:26:17', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '67c787d4-9f62-4acf-80e2-a5152adf7298' User entered 'Yes (Y)'	System	09 Sep 2020 17:26:56
	System	09 Sep 2020 17:26:56

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:26:42', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '67c787d4-9f62-4acf-80e2-a5152adf7298'	System	09 Sep 2020 17:26:56
User entered '50'	System	09 Sep 2020 17:26:56

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:26:49', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '67c787d4-9f62-4acf-80e2-a5152adf7298'	System	09 Sep 2020 17:26:56
User entered 'None (1)'	System	09 Sep 2020 17:26:56

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:26:54', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '67c787d4-9f62-4acf-80e2-a5152adf7298' User entered '09 Sep 2020 12:26'	System	09 Sep 2020 17:26:56
	System	09 Sep 2020 17:26:56

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 3'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:39', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '61dcd1ff-ce81-4f67-8de9-b924a05770d6'	System	10 Sep 2020 19:28:22
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 19:28:22

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:44', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '61dcd1ff-ce81-4f67-8de9-b924a05770d6' User entered 'Yes (Y)'	System	10 Sep 2020 19:28:22
	System	10 Sep 2020 19:28:22

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:55', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '61dcd1ff-ce81-4f67-8de9-b924a05770d6' User entered '90'	System	10 Sep 2020 19:28:22
	System	10 Sep 2020 19:28:22

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:27:59', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '61dcd1ff-ce81-4f67-8de9-b924a05770d6' User entered 'Yes (Y)'	System	10 Sep 2020 19:28:22
	System	10 Sep 2020 19:28:22

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '61dcd1ff-ce81-4f67-8de9-b924a05770d6' User entered '110'	System	10 Sep 2020 19:28:22
	System	10 Sep 2020 19:28:22

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:14', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '61dcd1ff-ce81-4f67-8de9-b924a05770d6'	System	10 Sep 2020 19:28:22
User entered 'None (1)'	System	10 Sep 2020 19:28:22

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:18', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '61dcd1ff-ce81-4f67-8de9-b924a05770d6' User entered '10 Sep 2020 14:28'	System	10 Sep 2020 19:28:22
	System	10 Sep 2020 19:28:22

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 4'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:19:03', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '414c8a36-fd2b-42c5-b33b-b02fdca03101'	System	11 Sep 2020 19:20:05
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 19:20:05

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:19:15', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '414c8a36-fd2b-42c5-b33b-b02fdca03101' User entered 'Yes (Y)'	System	11 Sep 2020 19:20:05
	System	11 Sep 2020 19:20:05

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:19:35', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '414c8a36-fd2b-42c5-b33b-b02fdca03101' User entered '140'	System	11 Sep 2020 19:20:05
	System	11 Sep 2020 19:20:05

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:19:41', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '414c8a36-fd2b-42c5-b33b-b02fdca03101' User entered 'Yes (Y)'	System	11 Sep 2020 19:20:05
	System	11 Sep 2020 19:20:05

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:19:51', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '414c8a36-fd2b-42c5-b33b-b02fdca03101' User entered '60'	System	11 Sep 2020 19:20:05
	System	11 Sep 2020 19:20:05

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:19:57', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '414c8a36-fd2b-42c5-b33b-b02fdca03101' User entered 'None (1)'	System	11 Sep 2020 19:20:05
	System	11 Sep 2020 19:20:05

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:01', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '414c8a36-fd2b-42c5-b33b-b02fdca03101' User entered '11 Sep 2020 14:20'	System	11 Sep 2020 19:20:05
	System	11 Sep 2020 19:20:05

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 5'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:08', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fa1830d6-db86-4228-9718-f7c64e33724e' User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:13', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fa1830d6-db86-4228-9718-f7c64e33724e' User entered 'Yes (Y)'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fa1830d6-db86-4228-9718-f7c64e33724e' User entered '170'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fa1830d6-db86-4228-9718-f7c64e33724e' User entered 'Yes (Y)'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:30', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fa1830d6-db86-4228-9718-f7c64e33724e' User entered '70'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:40', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fa1830d6-db86-4228-9718-f7c64e33724e' User entered 'None (1)'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:44', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fa1830d6-db86-4228-9718-f7c64e33724e' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 6'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:46:20', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf72f912-2f91-4c7b-a90f-b6f3e9293009'	System	13 Sep 2020 20:47:28
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:46:25', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf72f912-2f91-4c7b-a90f-b6f3e9293009' User entered 'Yes (Y)'	System	13 Sep 2020 20:47:28
	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:46:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf72f912-2f91-4c7b-a90f-b6f3e9293009' User entered '150'	System	13 Sep 2020 20:47:28
	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:46:38', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf72f912-2f91-4c7b-a90f-b6f3e9293009' User entered 'No (N)'	System	13 Sep 2020 20:47:28
	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:22', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf72f912-2f91-4c7b-a90f-b6f3e9293009' User entered 'None (1)'	System	13 Sep 2020 20:47:28
	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:25', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bf72f912-2f91-4c7b-a90f-b6f3e9293009' User entered '13 Sep 2020 15:47'	System	13 Sep 2020 20:47:28
	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 7'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:48:42', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b3b9368-1a5d-4676-815e-3aec17224001'	System	14 Sep 2020 19:49:10
User entered 'None (1)'	System	14 Sep 2020 19:49:10

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:48:46', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b3b9368-1a5d-4676-815e-3aec17224001' User entered 'Yes (Y)'	System	14 Sep 2020 19:49:10
	System	14 Sep 2020 19:49:10

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:48:52', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b3b9368-1a5d-4676-815e-3aec17224001' User entered '140'	System	14 Sep 2020 19:49:10
	System	14 Sep 2020 19:49:10

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b3b9368-1a5d-4676-815e-3aec17224001' User entered 'No (N)'	System	14 Sep 2020 19:49:10
	System	14 Sep 2020 19:49:10

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:04', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b3b9368-1a5d-4676-815e-3aec17224001'	System	14 Sep 2020 19:49:10
User entered 'None (1)'	System	14 Sep 2020 19:49:10

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2b3b9368-1a5d-4676-815e-3aec17224001' User entered '14 Sep 2020 14:49'	System	14 Sep 2020 19:49:10
	System	14 Sep 2020 19:49:10

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:39:58', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '797034ce-3e59-44cb-a0bd-e926cbea96b2' User entered 'None (0)'	System	08 Sep 2020 18:40:23
	System	08 Sep 2020 18:40:23

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:40:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '797034ce-3e59-44cb-a0bd-e926cbea96b2' User entered 'None (0)'	System	08 Sep 2020 18:40:23
	System	08 Sep 2020 18:40:23

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:40:02', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '797034ce-3e59-44cb-a0bd-e926cbea96b2' User entered 'None (0)'	System	08 Sep 2020 18:40:23
	System	08 Sep 2020 18:40:23

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:40:05', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '797034ce-3e59-44cb-a0bd-e926cbea96b2' User entered 'None (0)'	System	08 Sep 2020 18:40:23
	System	08 Sep 2020 18:40:23

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:40:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '797034ce-3e59-44cb-a0bd-e926cbea96b2' User entered 'None (0)'	System	08 Sep 2020 18:40:23
	System	08 Sep 2020 18:40:23

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:40:10', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '797034ce-3e59-44cb-a0bd-e926cbea96b2' User entered 'None (0)'	System	08 Sep 2020 18:40:23
	System	08 Sep 2020 18:40:23

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:40:15', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '797034ce-3e59-44cb-a0bd-e926cbea96b2' User entered 'No (N)'	System	08 Sep 2020 18:40:23
	System	08 Sep 2020 18:40:23

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T13:40:18', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '797034ce-3e59-44cb-a0bd-e926cbea96b2' User entered '08 Sep 2020 13:40'	System	08 Sep 2020 18:40:23
	System	08 Sep 2020 18:40:23

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 13:18'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 15:48'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:10:45', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '8894b25b-0add-4cf0-b7b5-9f493365d0ed' User entered 'None (0)'	System	09 Sep 2020 02:11:29
	System	09 Sep 2020 02:11:29

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:11:01', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '8894b25b-0add-4cf0-b7b5-9f493365d0ed'	System	09 Sep 2020 02:11:29
User entered 'No interference with activity (1)'	System	09 Sep 2020 02:11:29

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:11:06', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '8894b25b-0add-4cf0-b7b5-9f493365d0ed' User entered 'None (0)'	System	09 Sep 2020 02:11:29
	System	09 Sep 2020 02:11:29

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:11:10', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '8894b25b-0add-4cf0-b7b5-9f493365d0ed' User entered 'None (0)'	System	09 Sep 2020 02:11:29
	System	09 Sep 2020 02:11:29

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:11:14', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '8894b25b-0add-4cf0-b7b5-9f493365d0ed' User entered 'None (0)'	System	09 Sep 2020 02:11:29
	System	09 Sep 2020 02:11:29

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:11:16', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '8894b25b-0add-4cf0-b7b5-9f493365d0ed' User entered 'None (0)'	System	09 Sep 2020 02:11:29
	System	09 Sep 2020 02:11:29

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:11:20', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '8894b25b-0add-4cf0-b7b5-9f493365d0ed' User entered 'No (N)'	System	09 Sep 2020 02:11:29
	System	09 Sep 2020 02:11:29

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-08T21:11:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '8894b25b-0add-4cf0-b7b5-9f493365d0ed' User entered '08 Sep 2020 21:11'	System	09 Sep 2020 02:11:29
	System	09 Sep 2020 02:11:29

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '08 Sep 2020 16:43'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 2'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:27:09', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ebf9ad5a-a9dc-45d1-9401-0dcb1038829f'	System	09 Sep 2020 17:27:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Sep 2020 17:27:42

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:27:14', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ebf9ad5a-a9dc-45d1-9401-0dcb1038829f' User entered 'Some interference with activity (2)'	System	09 Sep 2020 17:27:42
	System	09 Sep 2020 17:27:42

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:27:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ebf9ad5a-a9dc-45d1-9401-0dcb1038829f' User entered 'Some interference with activity (2)'	System	09 Sep 2020 17:27:42
	System	09 Sep 2020 17:27:42

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:27:23', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ebf9ad5a-a9dc-45d1-9401-0dcb1038829f' User entered 'Some interference with activity (2)'	System	09 Sep 2020 17:27:42
	System	09 Sep 2020 17:27:42

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:27:29', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ebf9ad5a-a9dc-45d1-9401-0dcb1038829f' User entered 'None (0)'	System	09 Sep 2020 17:27:42
	System	09 Sep 2020 17:27:42

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:27:32', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ebf9ad5a-a9dc-45d1-9401-0dcb1038829f'	System	09 Sep 2020 17:27:42
User entered 'Some interference with activity not requiring medical attention (2)'	System	09 Sep 2020 17:27:42

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:27:37', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ebf9ad5a-a9dc-45d1-9401-0dcb1038829f' User entered 'No (N)'	System	09 Sep 2020 17:27:42
	System	09 Sep 2020 17:27:42

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-09T12:27:41', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ebf9ad5a-a9dc-45d1-9401-0dcb1038829f' User entered '09 Sep 2020 12:27'	System	09 Sep 2020 17:27:42
	System	09 Sep 2020 17:27:42

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 3'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:33', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd92dbd9d-34b2-461d-89ee-1b0fd3d63f2b'	System	10 Sep 2020 19:29:10
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:29:10

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:41', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd92dbd9d-34b2-461d-89ee-1b0fd3d63f2b'	System	10 Sep 2020 19:29:10
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:29:10

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:45', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd92dbd9d-34b2-461d-89ee-1b0fd3d63f2b'	System	10 Sep 2020 19:29:10
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:29:10

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:49', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd92dbd9d-34b2-461d-89ee-1b0fd3d63f2b'	System	10 Sep 2020 19:29:10
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:29:10

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:53', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd92dbd9d-34b2-461d-89ee-1b0fd3d63f2b' User entered 'None (0)'	System	10 Sep 2020 19:29:10
	System	10 Sep 2020 19:29:10

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:28:56', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd92dbd9d-34b2-461d-89ee-1b0fd3d63f2b' User entered 'None (0)'	System	10 Sep 2020 19:29:10
	System	10 Sep 2020 19:29:10

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:29:04', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd92dbd9d-34b2-461d-89ee-1b0fd3d63f2b' User entered 'No (N)'	System	10 Sep 2020 19:29:10
	System	10 Sep 2020 19:29:10

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-10T14:29:06', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd92dbd9d-34b2-461d-89ee-1b0fd3d63f2b' User entered '10 Sep 2020 14:29'	System	10 Sep 2020 19:29:10
	System	10 Sep 2020 19:29:10

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 4'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0ff019c7-199b-446e-a225-d3da91cf883f' User entered 'No interference with activity (1)'	System	11 Sep 2020 19:20:59
	System	11 Sep 2020 19:20:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:11', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0ff019c7-199b-446e-a225-d3da91cf883f' User entered 'No interference with activity (1)'	System	11 Sep 2020 19:20:59
	System	11 Sep 2020 19:20:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0ff019c7-199b-446e-a225-d3da91cf883f' User entered 'No interference with activity (1)'	System	11 Sep 2020 19:20:59
	System	11 Sep 2020 19:20:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:35', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0ff019c7-199b-446e-a225-d3da91cf883f' User entered 'Some interference with activity (2)'	System	11 Sep 2020 19:20:59
	System	11 Sep 2020 19:20:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:38', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0ff019c7-199b-446e-a225-d3da91cf883f' User entered 'None (0)'	System	11 Sep 2020 19:20:59
	System	11 Sep 2020 19:20:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:42', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0ff019c7-199b-446e-a225-d3da91cf883f' User entered 'None (0)'	System	11 Sep 2020 19:20:59
	System	11 Sep 2020 19:20:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:52', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0ff019c7-199b-446e-a225-d3da91cf883f' User entered 'No (N)'	System	11 Sep 2020 19:20:59
	System	11 Sep 2020 19:20:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-11T14:20:55', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0ff019c7-199b-446e-a225-d3da91cf883f' User entered '11 Sep 2020 14:20'	System	11 Sep 2020 19:20:59
	System	11 Sep 2020 19:20:59

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 5'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:51', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1855fb43-0f83-42c8-b8d9-bbfceb594c90'	System	12 Sep 2020 17:03:06
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:03:06

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:01:55', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1855fb43-0f83-42c8-b8d9-bbfceb594c90'	System	12 Sep 2020 17:03:06
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:03:06

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:02:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1855fb43-0f83-42c8-b8d9-bbfceb594c90'	System	12 Sep 2020 17:03:06
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:03:06

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:02:03', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1855fb43-0f83-42c8-b8d9-bbfceb594c90'	System	12 Sep 2020 17:03:06
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:03:06

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:02:07', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1855fb43-0f83-42c8-b8d9-bbfceb594c90' User entered 'None (0)'	System	12 Sep 2020 17:03:06
	System	12 Sep 2020 17:03:06

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:02:10', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1855fb43-0f83-42c8-b8d9-bbfceb594c90' User entered 'None (0)'	System	12 Sep 2020 17:03:06
	System	12 Sep 2020 17:03:06

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:02:14', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1855fb43-0f83-42c8-b8d9-bbfceb594c90' User entered 'No (N)'	System	12 Sep 2020 17:03:06
	System	12 Sep 2020 17:03:06

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-12T12:02:18', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1855fb43-0f83-42c8-b8d9-bbfceb594c90' User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:03:06
	System	12 Sep 2020 17:03:06

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 6'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:32', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c943859-0066-4cb5-a535-7de735183704'	System	13 Sep 2020 20:48:02
User entered 'No interference with activity (1)'	System	13 Sep 2020 20:48:02

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:37', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c943859-0066-4cb5-a535-7de735183704'	System	13 Sep 2020 20:48:02
User entered 'No interference with activity (1)'	System	13 Sep 2020 20:48:02

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:44', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c943859-0066-4cb5-a535-7de735183704'	System	13 Sep 2020 20:48:02
User entered 'No interference with activity (1)'	System	13 Sep 2020 20:48:02

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:47', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c943859-0066-4cb5-a535-7de735183704'	System	13 Sep 2020 20:48:02
User entered 'No interference with activity (1)'	System	13 Sep 2020 20:48:02

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:50', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c943859-0066-4cb5-a535-7de735183704' User entered 'None (0)'	System	13 Sep 2020 20:48:02
	System	13 Sep 2020 20:48:02

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:53', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c943859-0066-4cb5-a535-7de735183704' User entered 'None (0)'	System	13 Sep 2020 20:48:02
	System	13 Sep 2020 20:48:02

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:47:57', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c943859-0066-4cb5-a535-7de735183704' User entered 'No (N)'	System	13 Sep 2020 20:48:02
	System	13 Sep 2020 20:48:02

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-13T15:48:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9c943859-0066-4cb5-a535-7de735183704' User entered '13 Sep 2020 15:48'	System	13 Sep 2020 20:48:02
	System	13 Sep 2020 20:48:02

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	08 Sep 2020 18:27:09
User entered 'Day 7'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:13', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e5d2b5ce-2310-41de-9a3a-6adfe8f22a25' User entered 'None (0)'	System	14 Sep 2020 19:49:40
	System	14 Sep 2020 19:49:40

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:16', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e5d2b5ce-2310-41de-9a3a-6adfe8f22a25' User entered 'None (0)'	System	14 Sep 2020 19:49:40
	System	14 Sep 2020 19:49:40

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:20', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e5d2b5ce-2310-41de-9a3a-6adfe8f22a25' User entered 'None (0)'	System	14 Sep 2020 19:49:40
	System	14 Sep 2020 19:49:40

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:23', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e5d2b5ce-2310-41de-9a3a-6adfe8f22a25' User entered 'None (0)'	System	14 Sep 2020 19:49:40
	System	14 Sep 2020 19:49:40

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:26', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e5d2b5ce-2310-41de-9a3a-6adfe8f22a25' User entered 'None (0)'	System	14 Sep 2020 19:49:40
	System	14 Sep 2020 19:49:40

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:28', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e5d2b5ce-2310-41de-9a3a-6adfe8f22a25' User entered 'None (0)'	System	14 Sep 2020 19:49:40
	System	14 Sep 2020 19:49:40

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:35', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e5d2b5ce-2310-41de-9a3a-6adfe8f22a25' User entered 'No (N)'	System	14 Sep 2020 19:49:40
	System	14 Sep 2020 19:49:40

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-14T14:49:38', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e5d2b5ce-2310-41de-9a3a-6adfe8f22a25' User entered '14 Sep 2020 14:49'	System	14 Sep 2020 19:49:40
	System	14 Sep 2020 19:49:40

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:27:09

US3812132

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	13 Sep 2020 20:47:28
User entered 'Day 8'	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 09:50:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-15T23:59:48', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c848a2d6-30fb-427d-8156-603a2c6a93e3' User entered 'No (N)'	System	16 Sep 2020 05:00:03
	System	16 Sep 2020 05:00:03

US3812132

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 09:50:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-15T23:59:56', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c848a2d6-30fb-427d-8156-603a2c6a93e3' User entered '15 Sep 2020 23:59'	System	16 Sep 2020 05:00:03
	System	16 Sep 2020 05:00:03

US3812132

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	13 Sep 2020 20:47:28
User entered 'Day 8'	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:50:14

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)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-16T00:00:04', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ed57bc57-a0c3-4852-a226-331e24d3808a' User entered 'No (N)'	System	16 Sep 2020 05:00:18
	System	16 Sep 2020 05:00:18

US3812132

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:50:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-09-16T00:00:09', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ed57bc57-a0c3-4852-a226-331e24d3808a' User entered '16 Sep 2020 00:00'	System	16 Sep 2020 05:00:18
	System	16 Sep 2020 05:00:18

US3812132

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:50:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 20:47:28

US3812132

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:50:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 20:47:28

US3812132

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:10:09
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 21:15:45

US3812132

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:10:09
User entered '15 Sep 2020'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 21:15:45

US3812132

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:10:09
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 21:15:45

US3812132

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:10:09
User entered empty.	Karen Knapp (b) (4)	15 Sep 2020 21:15:45

US3812132

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:10:23
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 21:15:50

US3812132

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User entered '1'	System	15 Sep 2020 21:15:50

US3812132

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:11:10
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:16:45

US3812132

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:11:10
User entered '22 Sep 2020'	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:16:45

US3812132

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:11:10
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:16:45

US3812132

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:11:10
User entered empty.	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:16:45

US3812132

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:11:27
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:16:50

US3812132

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User entered '1'	System	22 Sep 2020 21:16:50

US3812132

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:11:56
User entered 'Yes (Y)'	Karen Knapp (b) (4)	30 Sep 2020 13:18:40

US3812132

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:11:56
User entered '29 Sep 2020'	Karen Knapp (b) (4)	30 Sep 2020 13:18:40

US3812132

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:11:56
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	30 Sep 2020 13:18:40

US3812132

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:11:56
User entered empty.	Karen Knapp (b) (4)	30 Sep 2020 13:18:40

US3812132

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:12:08
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	30 Sep 2020 13:18:44

US3812132

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User entered '1'	System	30 Sep 2020 13:18:44

US3812132

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:33
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:18

US3812132

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:33
User entered '5 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:18

US3812132

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:33
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:18

US3812132

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'VISIT3'	System	05 Oct 2020 18:40:18

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered '05 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered '11:28'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered '05 Oct 2020 11:28'	System	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered '97.4' F	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered '60'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'bpm'	System	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered '16'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'breaths/min'	System	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered '128'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'mmHg'	System	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:13:46
User entered '78'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered 'mmHg'	System	05 Oct 2020 18:40:38

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17

US3812132

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17

US3812132

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:14:34
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:50

US3812132

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:14:34
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:40:50

US3812132

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:14:48
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:41:01

US3812132

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:14:48
User entered '5 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:41:01

US3812132

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:14:48
User entered '11:40'	Breanna Galibert (b) (4) (b) (4)	05 Oct 2020 18:41:01

US3812132

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered '5 Oct 2020 11:40'	System	05 Oct 2020 18:41:01

US3812132

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:15:25
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	18 Oct 2020 15:45:58

US3812132

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:17
User entered '1'	System	18 Oct 2020 15:45:58

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 64'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-11T00:01:43', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a81c2b4b-ab81-414e-8261-8493408779aa' User entered 'No (N)'	System	11 Oct 2020 05:01:57
	System	11 Oct 2020 05:01:57

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-11T00:01:50', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a81c2b4b-ab81-414e-8261-8493408779aa' User entered 'No (N)'	System	11 Oct 2020 05:01:57
	System	11 Oct 2020 05:01:57

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-11T00:01:54', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a81c2b4b-ab81-414e-8261-8493408779aa' User entered '11 Oct 2020 00:01:54'	System	11 Oct 2020 05:01:57
	System	11 Oct 2020 05:01:57

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 71'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-20T11:49:05', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '45d8c221-9e33-495a-afef-a184ddc32952'	System	20 Oct 2020 16:49:26
User entered 'No (N)'	System	20 Oct 2020 16:49:26

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-20T11:49:16', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '45d8c221-9e33-495a-afef-a184ddc32952'	System	20 Oct 2020 16:49:26
User entered 'No (N)'	System	20 Oct 2020 16:49:26

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-20T11:49:22', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '45d8c221-9e33-495a-afef-a184ddc32952' User entered '20 Oct 2020 11:49:22'	System	20 Oct 2020 16:49:26
	System	20 Oct 2020 16:49:26

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 78'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-25T10:40:57', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0fb5f902-b681-4ec1-b4ee-fd12de2b1c4f' User entered 'No (N)'	System	25 Oct 2020 15:41:19
	System	25 Oct 2020 15:41:19

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-25T10:41:10', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0fb5f902-b681-4ec1-b4ee-fd12de2b1c4f' User entered 'No (N)'	System	25 Oct 2020 15:41:19
	System	25 Oct 2020 15:41:19

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-10-25T10:41:16', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0fb5f902-b681-4ec1-b4ee-fd12de2b1c4f' User entered '25 Oct 2020 10:41:16'	System	25 Oct 2020 15:41:19
	System	25 Oct 2020 15:41:19

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 92'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-09T15:46:15', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c49f6ccb-ca7b-47bb-b542-1a7e6e641cf1' User entered 'No (N)'	System	09 Nov 2020 20:46:34
	System	09 Nov 2020 20:46:34

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-09T15:46:25', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c49f6ccb-ca7b-47bb-b542-1a7e6e641cf1' User entered 'No (N)'	System	09 Nov 2020 20:46:34
	System	09 Nov 2020 20:46:34

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-09T15:46:29', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'c49f6ccb-ca7b-47bb-b542-1a7e6e641cf1' User entered '09 Nov 2020 15:46:29'	System	09 Nov 2020 20:46:34
	System	09 Nov 2020 20:46:34

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered 'Day 99'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-15T00:09:50', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '43b5a49e-8fb9-4e59-8f27-46f6e655d996'	System	15 Nov 2020 05:10:35
User entered 'No (N)'	System	15 Nov 2020 05:10:35

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-15T00:10:29', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '43b5a49e-8fb9-4e59-8f27-46f6e655d996'	System	15 Nov 2020 05:10:35
User entered 'No (N)'	System	15 Nov 2020 05:10:35

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-15T00:10:33', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '43b5a49e-8fb9-4e59-8f27-46f6e655d996' User entered '15 Nov 2020 00:10:33'	System	15 Nov 2020 05:10:35
	System	15 Nov 2020 05:10:35

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 22:32:13

US3812132

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:59
Data entry locked.	System	11 Aug 2020 22:32:13
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 22:32:13

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-22T01:03:09', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2e7ab96b-108b-4904-9436-dad25df79bbf'	System	22 Nov 2020 06:03:30
User entered 'No (N)'	System	22 Nov 2020 06:03:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-22T01:03:21', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2e7ab96b-108b-4904-9436-dad25df79bbf' User entered 'No (N)'	System	22 Nov 2020 06:03:30
	System	22 Nov 2020 06:03:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-22T01:03:25', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '2e7ab96b-108b-4904-9436-dad25df79bbf' User entered '22 Nov 2020 01:03:25'	System	22 Nov 2020 06:03:30
	System	22 Nov 2020 06:03:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-28T12:00:53', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3e65a4ba-e75c-4b1e-9980-bc2e7c13c4ab' User entered 'No (N)'	System	28 Nov 2020 18:02:21

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-28T12:02:03', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3e65a4ba-e75c-4b1e-9980-bc2e7c13c4ab'	System	28 Nov 2020 18:02:21
User entered 'No (N)'	System	28 Nov 2020 18:02:21

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-11-28T12:02:17', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '3e65a4ba-e75c-4b1e-9980-bc2e7c13c4ab' User entered '28 Nov 2020 12:02:17'	System	28 Nov 2020 18:02:21

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-03T09:39:40', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '801540b8-2a23-4e46-b1df-2d15634867aa' User entered 'No (N)'	System	03 Dec 2020 14:40:15
	System	03 Dec 2020 14:40:15

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-03T09:40:06', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '801540b8-2a23-4e46-b1df-2d15634867aa' User entered 'No (N)'	System	03 Dec 2020 14:40:15
	System	03 Dec 2020 14:40:15

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-03T09:40:13', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '801540b8-2a23-4e46-b1df-2d15634867aa' User entered '03 Dec 2020 09:40:13'	System	03 Dec 2020 14:40:15
	System	03 Dec 2020 14:40:15

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-10T00:32:01', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ad90b158-f9e8-4d88-84aa-61c0dd7c6073' User entered 'No (N)'	System	10 Dec 2020 05:32:30
	System	10 Dec 2020 05:32:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-10T00:32:17', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ad90b158-f9e8-4d88-84aa-61c0dd7c6073'	System	10 Dec 2020 05:32:30
User entered 'No (N)'	System	10 Dec 2020 05:32:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-10T00:32:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'ad90b158-f9e8-4d88-84aa-61c0dd7c6073' User entered '10 Dec 2020 00:32:24'	System	10 Dec 2020 05:32:30
	System	10 Dec 2020 05:32:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-17T15:17:06', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1cdc77cc-b774-4a7b-a022-699c0a1e696d' User entered 'No (N)'	System	17 Dec 2020 20:17:24
	System	17 Dec 2020 20:17:24

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-17T15:17:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1cdc77cc-b774-4a7b-a022-699c0a1e696d' User entered 'No (N)'	System	17 Dec 2020 20:17:24

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-17T15:17:22', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '1cdc77cc-b774-4a7b-a022-699c0a1e696d' User entered '17 Dec 2020 15:17:22'	System	17 Dec 2020 20:17:24
	System	17 Dec 2020 20:17:24

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-24T00:09:36', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '5f547b94-d6c4-4c42-8924-6d8810f7479a' User entered 'No (N)'	System	24 Dec 2020 05:09:48
	System	24 Dec 2020 05:09:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-24T00:09:39', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '5f547b94-d6c4-4c42-8924-6d8810f7479a'	System	24 Dec 2020 05:09:48
User entered 'No (N)'	System	24 Dec 2020 05:09:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-24T00:09:44', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '5f547b94-d6c4-4c42-8924-6d8810f7479a' User entered '24 Dec 2020 00:09:44'	System	24 Dec 2020 05:09:48
	System	24 Dec 2020 05:09:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-31T00:23:32', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '94392267-ccf9-4b0b-a153-a17e34b0a10f' User entered 'Yes (Y)'	System	31 Dec 2020 05:24:49
	System	31 Dec 2020 05:24:49

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-31T00:23:52', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '94392267-ccf9-4b0b-a153-a17e34b0a10f' User entered 'No (N)'	System	31 Dec 2020 05:24:49

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-31T00:24:01', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '94392267-ccf9-4b0b-a153-a17e34b0a10f' User entered 'No (N)'	System	31 Dec 2020 05:24:49
	System	31 Dec 2020 05:24:49

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-31T00:24:33', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '94392267-ccf9-4b0b-a153-a17e34b0a10f' User entered 'No (N)'	System	31 Dec 2020 05:24:49
	System	31 Dec 2020 05:24:49

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2020-12-31T00:24:46', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '94392267-ccf9-4b0b-a153-a17e34b0a10f' User entered '31 Dec 2020 00:24:46'	System	31 Dec 2020 05:24:49
	System	31 Dec 2020 05:24:49

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-07T08:10:31', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0fb997ff-6275-4034-b5b9-5ce1eb46d14e'	System	07 Jan 2021 13:10:48
User entered 'No (N)'	System	07 Jan 2021 13:10:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-07T08:10:36', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0fb997ff-6275-4034-b5b9-5ce1eb46d14e'	System	07 Jan 2021 13:10:48
User entered 'No (N)'	System	07 Jan 2021 13:10:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-07T08:10:42', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '0fb997ff-6275-4034-b5b9-5ce1eb46d14e' User entered '07 Jan 2021 08:10:42'	System	07 Jan 2021 13:10:48
	System	07 Jan 2021 13:10:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-14T13:41:57', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e0744824-1532-4066-88cf-bcb00d946836'	System	14 Jan 2021 18:42:16
User entered 'No (N)'	System	14 Jan 2021 18:42:16

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-14T13:42:01', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e0744824-1532-4066-88cf-bcb00d946836'	System	14 Jan 2021 18:42:16
User entered 'No (N)'	System	14 Jan 2021 18:42:16

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-14T13:42:12', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'e0744824-1532-4066-88cf-bcb00d946836' User entered '14 Jan 2021 13:42:12'	System	14 Jan 2021 18:42:16
	System	14 Jan 2021 18:42:16

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-21T09:35:36', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fe471a72-1676-46d0-ae18-1c8e52ff58da' User entered 'No (N)'	System	21 Jan 2021 14:35:48
	System	21 Jan 2021 14:35:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-21T09:35:41', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fe471a72-1676-46d0-ae18-1c8e52ff58da' User entered 'No (N)'	System	21 Jan 2021 14:35:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-21T09:35:45', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'fe471a72-1676-46d0-ae18-1c8e52ff58da' User entered '21 Jan 2021 09:35:45'	System	21 Jan 2021 14:35:48
	System	21 Jan 2021 14:35:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-28T10:34:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bc8ad2a7-594a-45b7-8ec0-f6c0266e0733'	System	28 Jan 2021 15:34:48
User entered 'No (N)'	System	28 Jan 2021 15:34:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-28T10:34:36', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bc8ad2a7-594a-45b7-8ec0-f6c0266e0733'	System	28 Jan 2021 15:34:48
User entered 'No (N)'	System	28 Jan 2021 15:34:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-01-28T10:34:45', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bc8ad2a7-594a-45b7-8ec0-f6c0266e0733' User entered '28 Jan 2021 10:34:45'	System	28 Jan 2021 15:34:48
	System	28 Jan 2021 15:34:48

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-08T09:47:44', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bd3d5683-b9e1-47cf-9c0f-adac3cdb3444'	System	08 Feb 2021 14:48:47
User entered 'Yes (Y)'	System	08 Feb 2021 14:48:47

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-08T09:47:57', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bd3d5683-b9e1-47cf-9c0f-adac3cdb3444'	System	08 Feb 2021 14:48:47
User entered 'No (N)'	System	08 Feb 2021 14:48:47

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-08T09:48:06', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bd3d5683-b9e1-47cf-9c0f-adac3cdb3444'	System	08 Feb 2021 14:48:47
User entered 'No (N)'	System	08 Feb 2021 14:48:47

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-08T09:48:19', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bd3d5683-b9e1-47cf-9c0f-adac3cdb3444'	System	08 Feb 2021 14:48:47
User entered 'Yes (Y)'	System	08 Feb 2021 14:48:47

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-08T09:48:28', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bd3d5683-b9e1-47cf-9c0f-adac3cdb3444'	System	08 Feb 2021 14:48:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Feb 2021 14:48:47

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-08T09:48:35', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'bd3d5683-b9e1-47cf-9c0f-adac3cdb3444'	System	08 Feb 2021 14:48:47
User entered '08 Feb 2021 09:48:35'	System	08 Feb 2021 14:48:47

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-13T12:45:20', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '84bef850-b51e-4b85-bcf2-7512aab2672e' User entered 'No (N)'	System	13 Feb 2021 17:45:30
	System	13 Feb 2021 17:45:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-13T12:45:24', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '84bef850-b51e-4b85-bcf2-7512aab2672e'	System	13 Feb 2021 17:45:30
User entered 'No (N)'	System	13 Feb 2021 17:45:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-13T12:45:27', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '84bef850-b51e-4b85-bcf2-7512aab2672e' User entered '13 Feb 2021 12:45:27'	System	13 Feb 2021 17:45:30
	System	13 Feb 2021 17:45:30

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-18T08:30:23', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '706d409e-9fb5-44c9-95db-a81ae95e4b7f' User entered 'No (N)'	System	18 Feb 2021 13:30:36
	System	18 Feb 2021 13:30:36

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-18T08:30:26', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '706d409e-9fb5-44c9-95db-a81ae95e4b7f' User entered 'No (N)'	System	18 Feb 2021 13:30:36

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-18T08:30:32', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '706d409e-9fb5-44c9-95db-a81ae95e4b7f' User entered '18 Feb 2021 08:30:32'	System	18 Feb 2021 13:30:36
	System	18 Feb 2021 13:30:36

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-25T08:29:42-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'b527e5de-14ec-4f90-915c-4ea1b560dca2'	System	25 Feb 2021 13:29:57
User entered 'No (N)'	System	25 Feb 2021 13:29:57

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-25T08:29:46-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'b527e5de-14ec-4f90-915c-4ea1b560dca2'	System	25 Feb 2021 13:29:57
User entered 'No (N)'	System	25 Feb 2021 13:29:57

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-02-25T08:29:52-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'b527e5de-14ec-4f90-915c-4ea1b560dca2'	System	25 Feb 2021 13:29:57
User entered '25 Feb 2021 13:29:52'	System	25 Feb 2021 13:29:57

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-04T01:00:04-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd772118d-0a3e-4f19-8bb5-0952fd7c836f'	System	04 Mar 2021 06:00:31
User entered 'No (N)'	System	04 Mar 2021 06:00:31

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-04T01:00:21-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd772118d-0a3e-4f19-8bb5-0952fd7c836f'	System	04 Mar 2021 06:00:31
User entered 'No (N)'	System	04 Mar 2021 06:00:31

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-04T01:00:27-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'd772118d-0a3e-4f19-8bb5-0952fd7c836f' User entered '04 Mar 2021 01:00:27'	System	04 Mar 2021 06:00:31
	System	04 Mar 2021 06:00:31

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-11T11:13:05-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9d801a3b-1f94-4872-8fbf-3f1721bf55dd'	System	11 Mar 2021 16:13:16
User entered 'No (N)'	System	11 Mar 2021 16:13:16

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-11T11:13:10-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9d801a3b-1f94-4872-8fbf-3f1721bf55dd'	System	11 Mar 2021 16:13:16
User entered 'No (N)'	System	11 Mar 2021 16:13:16

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-11T11:13:13-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '9d801a3b-1f94-4872-8fbf-3f1721bf55dd' User entered '11 Mar 2021 11:13:13'	System	11 Mar 2021 16:13:16
	System	11 Mar 2021 16:13:16

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-18T04:27:32-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6641d428-9531-4a94-8e24-1b62ef12d120'	System	18 Mar 2021 08:27:44
User entered 'No (N)'	System	18 Mar 2021 08:27:44

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-18T04:27:35-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6641d428-9531-4a94-8e24-1b62ef12d120'	System	18 Mar 2021 08:27:44
User entered 'No (N)'	System	18 Mar 2021 08:27:44

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-18T04:27:39-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6641d428-9531-4a94-8e24-1b62ef12d120'	System	18 Mar 2021 08:27:44
User entered '18 Mar 2021 04:27:39'	System	18 Mar 2021 08:27:44

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-25T08:43:24-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '5aa1505f-aa79-414f-a50f-89172eeb046f' User entered 'No (N)'	System	25 Mar 2021 12:43:37

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-25T08:43:29-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '5aa1505f-aa79-414f-a50f-89172eeb046f' User entered 'No (N)'	System	25 Mar 2021 12:43:37

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-25T08:43:32-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '5aa1505f-aa79-414f-a50f-89172eeb046f' User entered '25 Mar 2021 08:43:32'	System	25 Mar 2021 12:43:37
	System	25 Mar 2021 12:43:37

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-01T08:10:38-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '939fe23f-eb9e-4ff7-bfdc-060967946850' User entered 'No (N)'	System	01 Apr 2021 12:10:54

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-01T08:10:47-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '939fe23f-eb9e-4ff7-bfdc-060967946850' User entered 'No (N)'	System	01 Apr 2021 12:10:54

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-01T08:10:51-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '939fe23f-eb9e-4ff7-bfdc-060967946850'	System	01 Apr 2021 12:10:54
User entered '01 Apr 2021 08:10:51'	System	01 Apr 2021 12:10:54

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-08T00:05:08-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '100aecc3-fda0-4aed-ba19-7043fa966af0' User entered 'No (N)'	System	08 Apr 2021 04:05:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-08T00:05:10-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '100aecc3-fda0-4aed-ba19-7043fa966af0' User entered 'No (N)'	System	08 Apr 2021 04:05:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-08T00:05:14-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '100aecc3-fda0-4aed-ba19-7043fa966af0' User entered '08 Apr 2021 00:05:14'	System	08 Apr 2021 04:05:45
	System	08 Apr 2021 04:05:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-15T08:29:12-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a1b65614-be34-45c8-800a-56785dc44e30'	System	15 Apr 2021 12:29:25
User entered 'No (N)'	System	15 Apr 2021 12:29:25

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-15T08:29:16-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a1b65614-be34-45c8-800a-56785dc44e30'	System	15 Apr 2021 12:29:25
User entered 'No (N)'	System	15 Apr 2021 12:29:25

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-15T08:29:21-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: 'a1b65614-be34-45c8-800a-56785dc44e30'	System	15 Apr 2021 12:29:25
User entered '15 Apr 2021 08:29:21'	System	15 Apr 2021 12:29:25

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-22T00:02:31-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '51aa533e-63df-4c93-a721-599b98c24c29'	System	22 Apr 2021 04:03:19
User entered 'No (N)'	System	22 Apr 2021 04:03:19

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-22T00:02:35-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '51aa533e-63df-4c93-a721-599b98c24c29'	System	22 Apr 2021 04:03:19
User entered 'No (N)'	System	22 Apr 2021 04:03:19

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-04-22T00:02:38-04:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '51aa533e-63df-4c93-a721-599b98c24c29'	System	22 Apr 2021 04:03:19
User entered '22 Apr 2021 00:02:38'	System	22 Apr 2021 04:03:19

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:26:45

US3812132

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:26:45
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:26:45

US3812132

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:50:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-02T09:12:04-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6c53ebf7-e747-4a98-a54f-ca150ee8fcc9'	System	02 Mar 2021 14:12:14
User entered 'No (N)'	System	02 Mar 2021 14:12:14

US3812132

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:50:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (732BB0EF-EE73-4963-99B4-71C9F38205DC)', Time: '2021-03-02T09:12:11-05:00', User OID: 'PatientReportedOutcome (US3812132)', ODM File OID: '6c53ebf7-e747-4a98-a54f-ca150ee8fcc9' User entered '02 Mar 2021 09:12:11'	System	02 Mar 2021 14:12:14
	System	02 Mar 2021 14:12:14

US3812132

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:15:45
User entered 'Yes (Y)'	Karen Knapp (b) (4)	04 Nov 2020 14:26:15

US3812132

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:15:45
User entered '4 Nov 2020'	Karen Knapp (b) (4) (b) (4)	04 Nov 2020 14:26:15

US3812132

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:15:45
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	04 Nov 2020 14:26:15

US3812132

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:15:45
User entered empty.	Karen Knapp (b) (4) (b) (4)	04 Nov 2020 14:26:15

US3812132

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:15:57
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	04 Nov 2020 14:26:18

US3812132

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:55
User entered '1'	System	04 Nov 2020 14:26:18

US3812132

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:00:02

US3812132

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:00:02

US3812132

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:00:02

US3812132

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:07:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:00:02

US3812132

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:00:16

US3812132

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
User entered '1'	System	11 Dec 2020 17:00:16

US3812132

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:33:50

US3812132

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:33:50

US3812132

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:33:50

US3812132

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:33:50

US3812132

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:09
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:33:58

US3812132

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
User entered '1'	System	07 Jan 2021 22:33:58

US3812132

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:24:12

US3812132

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:12

US3812132

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Feb 2021 20:24:12

US3812132

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:12

US3812132

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:24:25

US3812132

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:22:01
User entered '1'	System	08 Feb 2021 20:24:25

US3812132

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:17
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	24 Mar 2021 19:43:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:17
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 14:37:06
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'date is correct, subject OOW, PD was created, subject unable to come to clinic during window.' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	10 Apr 2021 21:25:56
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Mar 2021 19:43:04
User entered '24 Mar 2021'	Gizelle Alvarez (b) (4) (b) (4)	24 Mar 2021 19:43:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[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 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:17
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4) (b) (4)	24 Mar 2021 19:43:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User entered 'VISIT4'	System	24 Mar 2021 19:43:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered '24 Mar 2021'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered '13:30'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User entered '24 Mar 2021 13:30'	System	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered '36.7' C	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered 'Other (Other)'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered 'tympanic'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered '60'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User entered 'bpm'	System	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered '14'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User entered 'breaths/min'	System	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered '135'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User entered 'mmHg'	System	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:10:20
User entered '86'	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User entered 'mmHg'	System	01 Apr 2021 17:31:04

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54

US3812132

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54

US3812132

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:10:23
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	24 Mar 2021 19:43:17

US3812132

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:10:23
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered '24 Mar 2021'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	24 Mar 2021 19:43:17

US3812132

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:10:25
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	24 Mar 2021 19:43:39

US3812132

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:10:25
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered '24 Mar 2021'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	24 Mar 2021 19:43:39

US3812132

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:10:25
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered '13:48'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	24 Mar 2021 19:43:39

US3812132

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User entered '24 Mar 2021 13:48'	System	24 Mar 2021 19:43:39

US3812132

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:10:28
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	24 Mar 2021 19:43:44

US3812132

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:54
User entered '1'	System	24 Mar 2021 19:43:44

US3812132

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
	(b) (4)	
User entered 'Yes (Y)'	Nia Moragne-O'Neal	06 Apr 2021 18:39:14
	(b) (4)	

US3812132

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User entered '6 Apr 2021'	(b) (4) Nia Moragne-O'Neal (b) (4)	06 Apr 2021 18:39:14

US3812132

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	06 Apr 2021 18:39:14

US3812132

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	06 Apr 2021 18:39:14

US3812132

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
	(b) (4)	
User entered 'Yes (Y)'	Nia Moragne-O'Neal	06 Apr 2021 18:39:17
	(b) (4)	

US3812132

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 18:39:17

US3812132

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:50:14

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:27
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'No (N)'	(b) (4) Heather Cherniawski (b) (4)	29 Oct 2020 19:30:53

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:08:50

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '4 Mar 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:08:50

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Clinic (Clinic)'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:08:50

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 18:08:50

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Mar 2021 18:09:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 18:09:09
User entered '4 Mar 2021' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:09:09
Amendment Manager: User opened query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 15:54:03
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:36:42

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lorna Sanchez McCann	04 Mar 2021 18:09:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 12:18:01
Query 'Data is required. Please complete.' answered with 'not done yet' (Site from System).	Andrea Wendrow (b) (4)	16 Feb 2021 16:51:20
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 16:37:22
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:08:34
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 09:39:23
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'done' (Site from DM).	Andrea Wendrow (b) (4)	10 Apr 2021 21:23:50
Signature has been broken.	Andrea Wendrow (b) (4)	10 Apr 2021 21:23:33
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	10 Apr 2021 21:23:33
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:32:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:36:42

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '4 Mar 2021' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:09:09
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:09:09
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:09:09
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:09:09
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:09:09
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
User entered empty.	System	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:50:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
User entered empty.	System	04 Feb 2021 16:37:22

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:09:28

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '4 Mar 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:09:28

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '12:00'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:09:28

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
User entered '4 Mar 2021 12:00'	System	04 Mar 2021 18:09:28

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:45
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:09:37

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:14

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:45
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '4 Mar 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:09:37

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:45
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '12:03'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Mar 2021 18:09:37

US3812132

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:43
User entered '4 Mar 2021 12:03'	System	04 Mar 2021 18:09:37

US3812132

Folder: **Unscheduled 14 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:50:14**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:21
User entered '14 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:30:54

US3812132

Folder: **Unscheduled 14 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:50:14**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:21
User entered '1'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:30:54

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:50:14

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:21
User entered '1'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:30:54

US3812132

Folder: **Unscheduled 14 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:50:14**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:21
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:30:54

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:50:14

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:21
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:30:54

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered '14 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered '14:35'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User entered '14 Sep 2020 14:35'	System	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered '97.1' F	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered '67'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User entered 'bpm'	System	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered '14'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User entered 'breaths/min'	System	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered '132'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User entered 'mmHg'	System	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:08:46
User entered '80'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:25

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12
User entered 'mmHg'	System	03 Oct 2020 16:31:25

US3812132

Folder: **Unscheduled 14 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:50:14**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12

US3812132

Folder: **Unscheduled 14 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:50:14**

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:12

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:09:01
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:34

US3812132

Folder: Unscheduled 14 Sep 2020

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:45:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:09:01
User entered '14 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:31:34

US3812132

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:50:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:55:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 16:30:33
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 14:53:18

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:34:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:34:41
Data point term sent to Coder	System	28 Sep 2020 16:34:06
User entered 'worsening anxiety'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '27 Aug 2020'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User entered empty.	System	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)' reason for change: New Information	Karen Knapp (b) (4)	30 Sep 2020 13:19:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '08 Sep 2020' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 21:36:31
User entered '21 Sep 2020' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	30 Sep 2020 13:19:23
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User entered empty.	System	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User closed query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity of greater than Grade 1/Mild. Please review and update severity as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:22:19
Query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity of greater than Grade 1/Mild. Please review and update severity as appropriate. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).	Maureen Dempsey (b) (4)	30 Oct 2020 22:18:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4)	30 Oct 2020 22:18:10
User opened query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity of greater than Grade 1/Mild. Please review and update severity as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 00:38:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	26 Apr 2021 16:36:56
Signature has been broken.	Marla Schwarber (b) (4)	22 Apr 2021 17:13:11
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '1'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Karen Knapp (b) (4) (b) (4)	30 Sep 2020 13:19:23
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User entered '0'	System	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34
User entered '1'	System	28 Sep 2020 16:33:07

US3812132

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:34

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User closed query 'Per DM CLR: Please review this worsening event and please note that there is no baseline MH or prior AE to support this worsening condition. Please review and update to record the baseline condition or update to remove the term worsening as appropriate. If confirmed as worsening, please update the severity, as worsening conditions are expected to be greater than Grade 1/Mild.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:14:15
Query 'Per DM CLR: Please review this worsening event and please note that there is no baseline MH or prior AE to support this worsening condition. Please review and update to record the baseline condition or update to remove the term worsening as appropriate. If confirmed as worsening, please update the severity, as worsening conditions are expected to be greater than Grade 1/Mild.' answered with 'MH UPDATED' (Site from DM).	Maureen Dempsey (b) (4)	30 Oct 2020 22:21:24
User opened query 'Per DM CLR: Please review this worsening event and please note that there is no baseline MH or prior AE to support this worsening condition. Please review and update to record the baseline condition or update to remove the term worsening as appropriate. If confirmed as worsening, please update the severity, as worsening conditions are expected to be greater than Grade 1/Mild.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 00:38:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:16:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:16:58
Data point term sent to Coder	System	28 Sep 2020 16:35:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'worsening GERD'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:35:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 16:35:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 16:35:02
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:34:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '27 Aug 2020'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User entered empty.	System	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)' reason for change: New Information	Karen Knapp (b) (4)	30 Sep 2020 13:20:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '08 Sep 2020' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 21:36:55
User entered '21 Sep 2020' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	30 Sep 2020 13:20:01
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User entered empty.	System	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User closed query 'Per CDM: As per precious query, please review the severity, as worsening conditions are expected to be greater than Grade 1/Mild. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:23:01
Query 'Per CDM: As per precious query, please review the severity, as worsening conditions are expected to be greater than Grade 1/Mild. Else clarify. Thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	21 Nov 2020 02:00:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4)	21 Nov 2020 02:00:39
User opened query 'Per CDM: As per precious query, please review the severity, as worsening conditions are expected to be greater than Grade 1/Mild. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:14:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '1'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Karen Knapp (b) (4)	30 Sep 2020 13:20:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User entered '0'	System	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39
User entered '1'	System	28 Sep 2020 16:34:50

US3812132

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:39

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User closed query 'Per MM, please review and confirm if the seriousness of the event is correct.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:25:04
Query 'Per MM, please review and confirm if the seriousness of the event is correct.' answered with 'PER INVESTIGATOR LD DERMATITIS WAS A GRADE 3 AT ONSET. SUBJECT BROUGHT IN FOR UNSCHEDULED VISIT TO ASSESS ARM.' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:33:56
User opened query 'Per MM, please review and confirm if the seriousness of the event is correct.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:24:00
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis, LLT: Dermatitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:54:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:54:38
Data point term sent to Coder	System	28 Sep 2020 16:37:21
User entered 'Dermatitis on left arm'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Dermatitis is not a solicited event for this study. Please review and update Was this a Solicited Adverse Reaction or update AE term to reflect the actual solicited event as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:24:59
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Dermatitis is not a solicited event for this study. Please review and update Was this a Solicited Adverse Reaction or update AE term to reflect the actual solicited event as appropriate. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:23:55
User entered 'No (N)' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:22:24
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Dermatitis is not a solicited event for this study. Please review and update Was this a Solicited Adverse Reaction or update AE term to reflect the actual solicited event as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 00:38:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '09 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Oct 2020 19:39:32
User entered '09:00' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	02 Oct 2020 19:39:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Sep 2020 16:37:53
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 16:37:53
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	28 Sep 2020 16:37:53
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 16:37:03
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User entered '09 Sep 2020 09:00'	System	02 Oct 2020 19:39:32
User entered '09 Sep 2020 UN:UN' (non-conformant).	System	28 Sep 2020 16:37:53
User entered empty.	System	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)' reason for change: New Information	Karen Knapp (b) (4)	30 Sep 2020 13:20:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '17 Sep 2020' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	02 Oct 2020 19:39:32
User entered '21 Sep 2020' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	30 Sep 2020 13:20:33
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '09:00' reason for change: New Information	Anya Penly (b) (4) (b) (4)	02 Oct 2020 19:39:32
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 13:21:08
User entered '08:00' reason for change: New Information	Karen Knapp (b) (4) (b) (4)	30 Sep 2020 13:21:08
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 13:20:33
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User entered '17 Sep 2020 09:00'	System	02 Oct 2020 19:39:32
User entered '21 Sep 2020 08:00'	System	30 Sep 2020 13:21:08
User entered empty.	System	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'Per CDM: per sponsor review, please confirm if this event is related to injection site and update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 09:55:15
Query 'Per CDM: per sponsor review, please confirm if this event is related to injection site and update accordingly' answered with 'PI CONFIRMS, RELATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	01 Dec 2020 23:32:49
User opened query 'Per CDM: per sponsor review, please confirm if this event is related to injection site and update accordingly' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 03:36:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Related (RELATED)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '1'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Karen Knapp (b) (4)	30 Sep 2020 13:20:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User entered '0'	System	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49
User entered '1'	System	28 Sep 2020 16:37:03

US3812132

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:49

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety aggravated - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 20:24:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 20:24:24
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 20:08:33
User entered 'worsening anxiety'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User entered empty.	System	05 Nov 2020 20:08:06

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 16:50:24
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Dec 2020 16:50:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 16:50:24
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Dec 2020 16:50:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User entered empty.	System	05 Nov 2020 20:08:06

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '1'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 16:50:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	11 Dec 2020 16:50:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

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 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:08:06
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User entered '0'	System	05 Nov 2020 20:08:06

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57
User entered '1'	System	05 Nov 2020 20:08:06

US3812132

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:57

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Bronchitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:14:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:14:24
Data point term sent to Coder	System	05 Nov 2020 20:13:45
User entered 'bronchitis'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '26 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User entered empty.	System	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '31 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User entered empty.	System	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '1'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:59:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User entered '0'	System	05 Nov 2020 20:13:30

US3812132

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56
User entered '1'	System	05 Nov 2020 20:13:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:07:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:48
User entered 'USA-US101-2021-mRNA-1273-P301000004'	System	15 Jan 2021 14:30:42
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 14:30:42
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 15:28:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'For coding purposes, HOSPITALIZATION FOR BARIATRIC SURGICAL PROCEDURE is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure' (Site from Coder).	(b) (4) (b) (4), (b) (6)	14 Mar 2021 20:22:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 13:58:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 13:58:59
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OBESITY. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:43:17
Data point term sent to Coder	System	04 Mar 2021 20:39:38
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OBESITY. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	04 Mar 2021 20:38:51
Coding entries removed.	Diana Bahena (b) (4) (b) (4)	04 Mar 2021 20:38:45
User entered 'Worsening OBESITY' reason for change: Per Query Resolution	Diana Bahena (b) (4) (b) (4)	04 Mar 2021 20:38:45
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OBESITY. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:01:55

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:01:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:01:59
Query 'For coding purposes, HOSPITALIZATION FOR BARIATRIC SURGICAL PROCEDURE is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure' answered with 'corrected' (Site from Coder).	Andrea Wendrow (b) (4) (b) (4)	14 Jan 2021 23:01:16
Data point term sent to Coder	System	14 Jan 2021 23:00:57
Coding entries removed.	Andrea Wendrow (b) (4) (b) (4)	14 Jan 2021 23:00:06
User entered 'Obesity' reason for change: Per Query Resolution	Andrea Wendrow (b) (4) (b) (4)	14 Jan 2021 23:00:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Metabolic surgery, LLT: Bariatric surgery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 13:13:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 13:13:01
User opened query 'For coding purposes, HOSPITALIZATION FOR BARIATRIC SURGICAL PROCEDURE is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure' (Site from Coder).	(b) (4), (b) (6) (b) (4)	13 Jan 2021 11:20:03
Data point term sent to Coder	System	11 Jan 2021 23:19:34
User entered 'Hospitalization for bariatric surgical procedure'	Andrea Wendrow (b) (4) (b) (4)	11 Jan 2021 23:18:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '24 Dec 2020'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty.	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '26 Dec 2020'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty.	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 23:18:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	14 Jan 2021 23:01:46
User entered 'Yes (Y)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	14 Jan 2021 23:01:46
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	14 Jan 2021 23:01:02
User closed query 'PV Query Urgent: Please confirm the subject was hospitalized for a 'planned' procedure. Please review protocol and update as applicable.' (Site from Safety).	System	14 Jan 2021 23:01:02
Query 'PV Query Urgent: Please confirm the subject was hospitalized for a 'planned' procedure. Please review protocol and update as applicable. ' answered with 'Updated per (b) (6) (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:28:25
User entered 'No (N)' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	12 Jan 2021 15:28:07
User opened query 'PV Query Urgent: Please confirm the subject was hospitalized for a 'planned' procedure. Please review protocol and update as applicable. ' (Site from Safety).	(b) (4)	12 Jan 2021 15:27:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Jan 2021 12:44:34
	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 13:46:05
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:36:30
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	14 Jan 2021 23:01:02
User entered '0' reason for change: Data Entry Error	Marla Schwarber (b) (4)	12 Jan 2021 15:27:53
User entered '1'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '24 Dec 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	14 Jan 2021 23:01:02
User entered empty; reason for change Per Query Resolution	Marla Schwarber (b) (4)	12 Jan 2021 15:27:53
User entered '24 Dec 2020'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '26 Dec 2020' reason for change: Per Query Resolution	(b) (4)	
	Andrea Wendrow (b) (4)	14 Jan 2021 23:01:02
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Marla Schwarber (b) (4)	12 Jan 2021 15:27:53
User entered '26 Dec 2020'	(b) (4)	
	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'No (N)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	14 Jan 2021 23:01:02
User entered empty; reason for change Per Query Resolution	Marla Schwarber (b) (4)	12 Jan 2021 15:27:53
User entered 'No (N)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty.	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Not Related (NOT RELATED)'	(b) (4) Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:56:41
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'no con med' (Site from DM).	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 19:27:33
User entered '0' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	19 Feb 2021 22:22:29
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:02:04
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '1'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty.	Andrea Wendrow (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:50:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'discharge summary received and uneventful. ' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 17:28:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:36:43
User entered 'Subject admitted 24Dec2020 for gastric sleeve surgery. Was hospitalized until 26Dec2020. Per subject hospital course uneventful. Discharge records pending'	Andrea Wendrow (b) (4) (b) (4)	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:01:46
User entered '0'	System	12 Jan 2021 15:27:53
User entered '1'	System	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Jan 2021 23:18:48

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:48
User entered 'USA-US101-2021-mRNA-1273-P301000006'	System	09 Feb 2021 13:27:44
User entered 'New'	(b) (4), (b) (6)	09 Feb 2021 13:27:44

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Postoperative abscess, LLT: Postoperative abscess - version MedDRA\23.0.	Coder Import (b) (4)	08 Mar 2021 11:05:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Mar 2021 11:05:03
Data point term sent to Coder	System	05 Mar 2021 17:37:37
User entered 'ABSCESS (post surgical ABDOMINAL)' reason for change: Data Entry Error	Diana Bahena (b) (4)	05 Mar 2021 17:37:08
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of ABSCESS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:43:33
Data point term sent to Coder	System	04 Mar 2021 20:40:40
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of ABSCESS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	Diana Bahena (b) (4)	04 Mar 2021 20:40:24
Coding entries removed.	Diana Bahena (b) (4)	04 Mar 2021 20:40:15
User entered 'ABSCESS (intraabdominal)' reason for change: Data Entry Error	Diana Bahena (b) (4)	04 Mar 2021 20:40:15
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of ABSCESS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:02:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Abscess, LLT: Abscess - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 16:35:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 16:35:34
Data point term sent to Coder	System	08 Feb 2021 16:35:01
User entered 'Abscess'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
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) (4), (b) (6)	08 Mar 2021 15:29:21
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 'Testing not done. ' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 17:28:51
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)	12 Feb 2021 14:33:58
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 16:24:10
DataPoint Un-verified.	Marla Schwarber (b) (4)	22 Apr 2021 17:16:24
	(b) (4)	
Signature has been broken.	Marla Schwarber (b) (4)	22 Apr 2021 17:16:24
	(b) (4)	
User entered '29 Jan 2021' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	22 Apr 2021 17:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
	(b) (4)	
User entered '30 Jan 2021'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty.	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (29 Jan 2021, when family member tried to drain abscess). If not updating the start date, please clarify.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:46:01
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (29 Jan 2021, when family member tried to drain abscess). If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:35:26
User entered empty.	System	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Diana Bahena (b) (4)	04 Mar 2021 20:42:31
User entered 'Yes (Y)'	(b) (4)	
	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46
	(b) (4)	

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	04 Mar 2021 20:42:31
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	04 Mar 2021 20:42:31
User entered '06 Feb 2021' reason for change: Data Entry Error	Diana Bahena (b) (4)	04 Mar 2021 20:42:31
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	04 Mar 2021 20:41:32
User entered empty.	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:46:09
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:34:22
User entered empty.	System	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Grade 4 (Grade 4)'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '1'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '30 Jan 2021'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '06 Feb 2021'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty.	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '0'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '1'	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:43:46
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'no procedure was performed' (Site from DM).	Diana Bahena (b) (4) (b) (4)	04 Mar 2021 20:41:09
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:02:21
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:29:39
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	04 Mar 2021 20:42:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	04 Mar 2021 20:41:32
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:35:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Wendrow (b) (4) (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered empty.	Andrea Wendrow (b) (4)	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:03
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:30:00
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Labs/diagnostics not included on discharge summary. Straight forward admission.' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 17:37:40
User entered 'SUBJECT DEVELOPED ABSCESS NEAR PREVIOUS SURGICAL INCISION. FAMILY MEMBER TRIED TO DRAIN ON 29JAN2021, WENT TO ER 30JAN2021 AND WAS ADMITTED FOR IV ANTIBIOTICS AND DRAIN PLACEMENT. DISCHARGED WITH PO AND IV ANTIBIOTICS FOR 1 WEEK ON 06FEB2021. RECORDS PENDING' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 17:37:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:34:49

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject developed abscess near previous surgical incision. Family member tried to drain on 29Jan2021, went to ER 30Jan2021 and was admitted for IV antibiotics and drain placement. Discharged with po and IV antibiotics for 1 week on 06Feb2021. Records pending'	Andrea Wendrow (b) (4)	(b) (4) 08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 16:34:46

US3812132

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Feb 2021 16:34:46

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:50:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:40
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2 (09SEP2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 06:02:41
Query 'Per DM CLR: Per Diary Dose 2 Day 2 (09SEP2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'Tylenol listed in Con Meds for noted time frame' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	12 Mar 2021 22:27:46
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2 (09SEP2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 07:48:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:59:18

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:50:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Reason for treating pain/fever Medication is recorded as 'Yes' for Record #3-4 (Dated 09Sep2020-11Sep2020), Temperature day form, Diary Dose 2 folder; However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:33:29
Query 'Per CDM: Reason for treating pain/fever Medication is recorded as 'Yes' for Record #3-4 (Dated 09Sep2020-11Sep2020), Temperature day form, Diary Dose 2 folder; However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' answered with 'updated conmeds' (Site from DM).	Anya Penly (b) (4)	02 Oct 2020 19:41:17
User opened query 'Per CDM: Reason for treating pain/fever Medication is recorded as 'Yes' for Record #3-4 (Dated 09Sep2020-11Sep2020), Temperature day form, Diary Dose 2 folder; However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 11:24:14
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	24 Aug 2020 14:28:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:29:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:29:43
Data point term sent to Coder	System	24 Aug 2020 14:28:59
User entered 'ALPRAZOLAM'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'ANXIETY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '.5'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2015'	Breanna Galibert (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User closed query 'Per DM CLR: Please review if a stop date should be recorded as there is another CM of Alprazolam (CM#25) which started on 26 Oct 2020. If yes, please update CM stop date as applicable. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:34:07
Query 'Per DM CLR: Please review if a stop date should be recorded as there is another CM of Alprazolam (CM#25) which started on 26 Oct 2020. If yes, please update CM stop date as applicable. Otherwise, provide clarification. ' answered with 'done' (Site from DM).	Andrea Wendrow (b) (4)	12 Apr 2021 22:14:54
DataPoint Un-verified.	Andrea Wendrow (b) (4)	12 Apr 2021 22:14:36
User entered 'No (N)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	12 Apr 2021 22:14:36
User opened query 'Per DM CLR: Please review if a stop date should be recorded as there is another CM of Alprazolam (CM#25) which started on 26 Oct 2020. If yes, please update CM stop date as applicable. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 21:26:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
DataPoint Un-verified.	Andrea Wendrow (b) (4)	12 Apr 2021 22:14:36
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Apr 2021 22:14:36
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User entered '1'	System	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User entered '1'	System	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:30
User entered '804 (804)'	System	24 Aug 2020 14:28:56

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:29:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:30:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:30:34
Data point term sent to Coder	System	24 Aug 2020 14:30:02
User entered 'TRAZADONE'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'INSOMNIA'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '50'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2014'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:29:35

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:29:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:31:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:31:39
Data point term sent to Coder	System	24 Aug 2020 14:31:04
User entered 'METOPROLOL'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'HYPERTENSION'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '100'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2018'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:30:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:28:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 15:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 15:06:49
Data point term sent to Coder	System	24 Aug 2020 14:32:06
User entered 'TAMULUSIN'	Breanna Galibert (b) (4)	24 Aug 2020 14:31:54
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User closed query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:22:40
Query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' answered with 'Per Investigator: Subject denies any diagnosis for this conmed. Also, medical records do not report any diagnosis for this conmed. continue to report medication as preventative prostate health.' (Site from DM).	Anya Penly (b) (4)	05 Oct 2020 14:15:36
	(b) (4)	
User opened query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:43:30
User entered 'PREVENTATIVE PROSTATE HEALTH'	Breanna Galibert (b) (4)	24 Aug 2020 14:31:54
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '.4'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2016'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:31:54

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:28:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:54:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:54:00
Data point term sent to Coder Coding entries removed.	System Maureen Dempsey (b) (4)	30 Oct 2020 22:25:23 30 Oct 2020 22:25:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 22:48:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 22:48:42
Data point term sent to Coder User entered 'CELECOXIB'	System Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:06 24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User closed query 'Per DM CLR: Please review the indication to include the specific type of ARTHRITIS IN HANDS (e.g. Osteoarthritis, Gouty, Rheumatoid, etc.). Reconcile and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:28:26
Query 'Per DM CLR: Please review the indication to include the specific type of ARTHRITIS IN HANDS (e.g. Osteoarthritis, Gouty, Rheumatoid, etc.). Reconcile and update as appropriate, otherwise clarify. ' answered with 'UPDATED' (Site from DM).	Maureen Dempsey (b) (4)	30 Oct 2020 22:25:34
User entered 'OSTEOARTHRITIS IN BOTH HANDS' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review the indication to include the specific type of ARTHRITIS IN HANDS (e.g. Osteoarthritis, Gouty, Rheumatoid, etc.). Reconcile and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:54:37
User entered 'ARTHRITIS IN HANDS'	Breanna Galibert (b) (4)	24 Aug 2020 14:32:50
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '200'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2016'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:32:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:28:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 13:32:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 13:32:05
Data point term sent to Coder	System	24 Aug 2020 14:34:07
User entered 'BUPOPION XL'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'DEPRESSION'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '300'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2018'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:33:32

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:27:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 17:50:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 17:50:56
Data point term sent to Coder Coding entries removed.	System Anya Penly (b) (4) (b) (4)	08 Sep 2020 17:49:23 08 Sep 2020 17:49:17
User entered 'Hydrochlorothiazide' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	08 Sep 2020 17:49:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:09:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:09:41
Data point term sent to Coder	System	24 Aug 2020 14:35:08
User entered 'HYDRO CHLOROTHIER'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'HYPERTENSION'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '25'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2015'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:46:10
User entered 'No (N)' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:46:10
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:46:10
User entered '20 Feb 2021' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:46:10
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User entered '1'	System	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User entered '1'	System	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:23
User entered '804 (804)'	System	24 Aug 2020 14:34:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:16:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:16:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON TRIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:35:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:35:44
Data point term sent to Coder	System	24 Aug 2020 14:35:09
User entered 'IRON'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'GENERAL HEALTH'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '324'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2019'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:46:52
User entered 'No (N)' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:46:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:46:52
User entered '20 Feb 2021' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:46:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User entered '1'	System	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User entered '1'	System	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User entered '804 (804)'	System	24 Aug 2020 14:35:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:27:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:36:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:36:31
Data point term sent to Coder	System	24 Aug 2020 14:36:09
User entered 'MULTIVITAMIN'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'GENERAL HEALTH'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '1'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Lyly Dang (b) (4)	06 Nov 2020 18:54:53
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:04:18
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'updated' (Site from DM).	Lyly Dang (b) (4)	06 Nov 2020 18:54:59
User entered empty; reason for change Data Entry Error	Lyly Dang (b) (4)	06 Nov 2020 18:54:53
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:59:48
User entered 'PILL'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2019'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 21:29:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 21:29:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Jan 2021 21:29:25
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Jan 2021 21:28:00
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Jan 2021 21:28:00
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 21:28:00
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Jan 2021 21:27:40
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 21:27:40
User entered '26 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 21:27:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User entered '1'	System	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User entered '1'	System	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User entered '804 (804)'	System	24 Aug 2020 14:35:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:26:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:30:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:30:24
Data point term sent to Coder	System	05 Oct 2020 14:17:00
Coding entries removed.	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:16:29
User entered 'D3 (250mcg) / K2 (1500mcg)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:16:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: COLECALCIFEROL;MENAQUINONE, PRODUCTSYNONYM: D3 +K2 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:13:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:13:46
Data point term sent to Coder	System	24 Aug 2020 14:37:11
User entered 'D3 & K2'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'VITAMIN D DEFICIENCY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:31:58
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'Corrected per Investigator.' (Site from DM).	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:16:46
User entered '1' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:16:29
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:40:36
User entered '250'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:16:29
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2017'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:36:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:26:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:03:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:03:33
Data point term sent to Coder	System	24 Aug 2020 14:37:14
User entered 'XYZAL 24HR'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'ENVIRONMENTAL ALLERGIES'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '5'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'UN UNK 2015'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:37:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:26:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: QUERCETIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:22:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:22:35
Data point term sent to Coder	System	24 Aug 2020 14:38:14
User entered 'QUERCETIN'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'GENERAL HEALTH'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '800'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered '6X/DAY'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:29:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:26:02
User entered 'UN UNK 2018'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:26:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:57
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 14:37:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:24:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 14:40:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	24 Aug 2020 14:40:38
Data point term sent to Coder	System	24 Aug 2020 14:39:15
User entered 'ALBUTEROL INHALER'	Breanna Galibert (b) (4)	24 Aug 2020 14:38:38
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:58
User entered 'ASTHMA'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:05
User entered '2'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:09
User entered 'puff (PUFF)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:11
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:13
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:18
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:25:20
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:23:46
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated MH with correct start date per source.' (Site from DM).	Anya Penly (b) (4)	05 Oct 2020 14:42:14
	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:38:50
User entered 'UN UNK 1990'	Breanna Galibert (b) (4)	24 Aug 2020 14:38:38
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:22
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:25
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:27
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 14:38:38

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 08:11:19
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 Oct 2020 08:11:19
Data point term sent to Coder	System	05 Oct 2020 14:45:07
Coding entries removed.	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:44:52
User entered 'SYMBICORT [Budesonide 80mcg, formoterol fumarate dihydrate 4.5mcg]' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:44:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:40:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:40:58
Data point term sent to Coder	System	24 Aug 2020 14:40:19
User entered 'SYMBICORT'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:15
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:17
User entered 'ASTHMA'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:20
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:32:11
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' answered with 'added dosage for each component in name of medication.' (Site from DM).	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:45:15
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:42:48
User entered '2'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:22
User entered 'puff (PUFF)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:26
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:28
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:30
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:31
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:33
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:23:40
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated MH with correct start date per source.' (Site from DM).	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:42:35
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:43:02
User entered 'UN UNK 1990'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:35
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 16:44:13
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Dec 2020 16:44:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:24:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 16:44:13
User entered '26 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Dec 2020 16:44:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:24:38
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:24:39
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User entered '1'	System	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User entered '1'	System	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:03
User entered '804 (804)'	System	24 Aug 2020 14:39:22

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Apr 2021 08:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Apr 2021 08:07:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:23
Data point term sent to Coder	System	16 Apr 2021 15:01:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	16 Apr 2021 15:01:28
Coding entries removed.	(b) (4)	
	Marla Schwarber (b) (4)	16 Apr 2021 15:01:28
User entered 'AZELASTINE 0.15%' reason for change: Data Entry Error	Marla Schwarber (b) (4)	16 Apr 2021 15:01:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:23:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: AZELASTINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 21:32:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 21:32:42
Data point term sent to Coder	System	24 Aug 2020 14:40:20
User entered 'AZELASTINE'	Breanna Galibert (b) (4)	24 Aug 2020 14:40:20
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:24
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:27
User entered 'ENVIRONMENTAL ALLERGIES'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User closed query 'Per CDM re-query: Response noted; Please provide only the numerical value (eg: 0.1) without the unit (eg: %) in the dose field. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:23
Query 'Per CDM re-query: Response noted; Please provide only the numerical value (eg: 0.1) without the unit (eg: %) in the dose field. Thank you. ' answered with 'updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 15:04:37
User entered '411' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 15:04:20
User entered '1' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 15:01:28
User closed query 'Per CDM re-query: 0.1% is the strength of the medication. Please provide the strength along with the medication name and provide the actual dose of medication in Dose per administration field as there are multiple dosage options available for this drug. Please update else clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:33:14
User opened query 'Per CDM re-query: Response noted; Please provide only the numerical value (eg: 0.1) without the unit (eg: %) in the dose field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:33:11
Query 'Per CDM re-query: 0.1% is the strength of the medication. Please provide the strength along with the medication name and provide the actual dose of medication in Dose per administration field as there are multiple dosage options available for this drug. Please update else clarify in query response. ' answered with 'This is the name and the actual dose of the medication' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	15 Apr 2021 19:47:28
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:45:17

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: 0.1% is the strength of the medication. Please provide the strength along with the medication name and provide the actual dose of medication in Dose per administration field as there are multiple dosage options available for this drug. Please update else clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:45:11
Query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Diana Bahena (b) (4)	14 Apr 2021 19:52:00
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:51:53
User entered '0.1%' reason for change: Data Entry Error	Diana Bahena (b) (4)	14 Apr 2021 19:51:53
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 21:26:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:23:29
User entered '1'	Breanna Galibert (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
DataPoint Un-verified.	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 15:04:20
User entered 'ug (ug)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 15:04:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:23:30
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 15:04:20
DataPoint Un-verified.	Diana Bahena (b) (4) (b) (4)	14 Apr 2021 19:51:53
User entered '1 spray per nostril' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	14 Apr 2021 19:51:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:23:32
User entered 'SPRAY/NOSTRIL'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:34
User entered 'twice daily (BID)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:35
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:37
User entered 'Nasal (NASAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:38
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:40
User entered 'UN UNK 2016'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:42
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:43
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:23:46
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:40:20

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:21:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 14:41:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	24 Aug 2020 14:41:43
Data point term sent to Coder	System	24 Aug 2020 14:41:24
User entered 'FLONASE'	Breanna Galibert (b) (4)	24 Aug 2020 14:41:16
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:49
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:50
User entered 'ENVIRONMENTAL ALLERGIES'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:52
User entered '1'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:54
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:55
User entered 'SPRAY/NOSTRIL'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:57
User entered 'twice daily (BID)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:22:01
User entered 'Nasal (NASAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:22:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:22:04
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:22:39
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated mh start date per source' (Site from DM).	Anya Penly (b) (4) (b) (4)	05 Oct 2020 14:45:37
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:41:50
User entered 'UN UNK 1990'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:22:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:22:07
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:22:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:22:11
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:41:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:21:10
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 15:05:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 15:05:33
Data point term sent to Coder	System	24 Aug 2020 14:43:26
User entered 'TESTOSTERONE CREAM'	Breanna Galibert (b) (4)	24 Aug 2020 14:42:33
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:11
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:13
User entered 'TESTICULAR HYPOFUNCTION'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:17
User entered '2'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:16
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:19
User entered 'PUMPS'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:21
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:23
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:24
User entered 'Topical (TOPICAL)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:26
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:28
User entered 'UN Aug 2011'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:30
User entered '0'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:32
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:34
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:21:35
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:42:33

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:44:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:44:48
Data point term sent to Coder	System	28 Sep 2020 16:26:49
User entered 'buspirone'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:20:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:27
User entered 'worsening anxiety'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:20:28
User entered '5'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:30
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:20:31
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:32
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:20:34
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:20:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:20:37
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:20:11
User entered '27 Aug 2020'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:20:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:18
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:21:26
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Lyly Dang (b) (4) (b) (4)	06 Nov 2020 18:56:36
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	06 Nov 2020 18:56:26
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:02:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:14
User entered '08 Sep 2020' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	06 Nov 2020 18:56:26
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:40
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:15:18
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'MEDICATION ADDED SEE AE#3' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:27:24
User entered 'No (N)' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:27:05
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 20:59:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User entered '1'	System	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User entered '1'	System	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:56
User entered '804 (804)'	System	28 Sep 2020 16:26:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE, PRODUCTSYNONYM: EPIPEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 13:58:25
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 13:58:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:19:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: ALPHA- AND BETA-ADRENORECEPTOR AGONISTS, PRODUCT: EPINEPHRINE, PRODUCTSYNONYM: EPIPEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:56:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:56:42
Data point term sent to Coder	System	28 Sep 2020 16:27:51
User entered 'Epipen'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:51
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:49
User entered 'penicillin allergy'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:47
User entered '0.3'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:19:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:19:46
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'DOSAGE IS CORRECT AS ENTERED' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	30 Oct 2020 22:29:10
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 20:59:44
User entered 'mL (mL)'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:44
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:42
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:19:39
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:38
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:36
User entered 'un UNK 2017'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:34
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:31
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:19:29
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:27:09

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:10:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROTIGOTINE, PRODUCTSYNONYM: NEUPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:29:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:29:45
Data point term sent to Coder	System	28 Sep 2020 16:28:55
User entered 'neupro'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:10:49
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:10:51
User entered 'restless leg syndrome'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:10:53
User entered '3'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:10:55
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:10:57
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:10:59
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:11:01
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:11:02
User entered 'Transdermal (TRANSDERMAL)'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:11:05
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:11:06
User entered 'un UNK 2019'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:11:07
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:22:38
User entered 'No (N)' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:11:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:22:38
User entered '24 Feb 2021' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:11:14
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:11:16
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User entered '1'	System	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User entered '1'	System	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:40
User entered '804 (804)'	System	28 Sep 2020 16:28:37

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:08:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:30:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:30:37
Data point term sent to Coder	System	28 Sep 2020 16:31:02
User entered 'omeprazole'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:09:03
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:09:13
User entered 'worsening gerd'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:09:34
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 14:09:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:09:17
User entered '40'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:09:23
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:09:44
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:09:51
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:09:53
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:09:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:10:01
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:10:03
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:47:38
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' answered with 'UPDATED' (Site from DM).	Maureen Dempsey (b) (4)	30 Oct 2020 22:35:48
	(b) (4)	
User entered '27 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	30 Oct 2020 22:35:43
	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 21:04:15
User entered '24 Aug 2020'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:10:05
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User closed query 'Per CDM re-query: Thank you for the response. As the AE ended on 08 SEP, please confirm the medication is still ongoing or not. If the subject stopped taking medication, please provide end date. Else confirm the medication ongoing in query response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 08:31:29
Query 'Per CDM re-query: Thank you for the response. As the AE ended on 08 SEP, please confirm the medication is still ongoing or not. If the subject stopped taking medication, please provide end date. Else confirm the medication ongoing in query response. ' answered with 'medication still ongoing' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	15 Apr 2021 19:49:11
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:42:48
User opened query 'Per CDM re-query: Thank you for the response. As the AE ended on 08 SEP, please confirm the medication is still ongoing or not. If the subject stopped taking medication, please provide end date. Else confirm the medication ongoing in query response. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:42:46
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'condition has improved due to increase in medication dosing, but medication dosing still the same. ' (Site from DM).	Diana Bahena (b) (4) (b) (4)	14 Apr 2021 20:12:33
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 21:28:06

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:10:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:10:09
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:10:12
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 16:30:15

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:44:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:44:51
Data point term sent to Coder	System	02 Oct 2020 19:44:01
User entered 'tylenol'	Any Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:33
User entered 'No (N)'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE AND PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 07:37:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE AND PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'SOLICITED EVENT, DOES NOT MEET CRITERIA FOR AE PER PI' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Nov 2020 18:56:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:18:30

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE AND PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:55:19
User entered 'headache and pain at injection site'	Anya Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:27
User entered '500'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:25
User entered 'mg (mg)'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:23
User entered empty.	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:21
User entered 'three times daily (TID)'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:19
User entered empty.	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:18
User entered 'Oral (ORAL)'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:16
User entered empty.	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:18:13
User entered '9 Sep 2020'	Anyia Penly (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:12
User entered '0'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:10
User entered 'No (N)'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:09
User entered '11 Sep 2020'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:07
User entered 'Yes (Y)'	Anyia Penly (b) (4) (b) (4)	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User entered '3'	System	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User entered '1'	System	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:30
User entered '804 (804)'	System	02 Oct 2020 19:44:00

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:04:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: ANORO ELLIPTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:21:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:21:26
Data point term sent to Coder	System	05 Nov 2020 20:21:05
User entered 'anoro ellipta'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:04:36
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:04:38
User entered 'Bronchitis'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:04:40
User entered '62.5/25'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:04:53
User entered 'ug (ug)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:04:54
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:04:56
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:05:05
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:05:08
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:05:10
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:05:12
User entered '26 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:05:14
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 07:50:36
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'Was switched from Symbicort to Anoro secondary to repeated episodes of oral thrush. His use is for the treatment of chronic asthma.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 16:47:53
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:19:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:05:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:05:17
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:05:18
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:20:24

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:05:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:49:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:49:27
Data point term sent to Coder	System	05 Nov 2020 20:22:07
User entered 'alprazolam'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:02
User entered 'worsening anxiety'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:06
User entered '.5'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:07
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:06:11
User entered 'twice daily (BID)'	Breanna Galibert (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:06:12
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:14
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:15
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:17
User entered '26 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:20
User entered '0'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:53:42
User entered 'No (N)' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:53:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	13 Apr 2021 14:35:28
' (Site from DM).		
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	Andrea Wendrow (b) (4)	12 Apr 2021 22:13:13
' answered with 'still has baseline anxiety' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	30 Jan 2021 21:29:32
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:06:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	06 Nov 2020 18:55:31
User entered 'No (N)'	Breanna Galibert (b) (4)	05 Nov 2020 20:21:19
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:53:42
User entered '01 Jan 2021' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:53:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:06:23
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Nov 2020 18:55:31
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	05 Nov 2020 20:21:19
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:25
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User entered '2'	System	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User entered '1'	System	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:18
User entered '804 (804)'	System	05 Nov 2020 20:21:19

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:23:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:23:37
Data point term sent to Coder	System	05 Nov 2020 20:22:08
User entered 'buspirone'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:36
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:38
User entered 'worsening anxiety'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:41
User entered '5'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:43
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:46
User entered 'twice daily (BID)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:48
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:50
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:06:51
User entered empty.	Breanna Galibert (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:06:53
User entered '26 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:06:54
User entered '0'	Breanna Galibert (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:54:29
User entered 'No (N)' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:54:29
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	15 Apr 2021 11:48:56
' (Site from DM).		
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	Diana Bahena (b) (4)	14 Apr 2021 20:13:02
' answered with 'AE resolved due to medication dose increase, but still on same dose of medication' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	30 Jan 2021 21:30:06
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:06:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Nov 2020 20:22:02
	(b) (4)	

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
DataPoint Un-verified.	Marla Schwarber (b) (4)	19 Apr 2021 21:54:29
User entered '01 Jan 2021' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	19 Apr 2021 21:54:29
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:06:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User entered '2'	System	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User entered '1'	System	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:15
User entered '804 (804)'	System	05 Nov 2020 20:22:02

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:32:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:32:42
Data point term sent to Coder	System	11 Jan 2021 21:31:34
User entered 'Bariatric Multivitamin'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:09:23
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	15 Mar 2021 06:02:57
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	Marla Schwarber (b) (4)	12 Mar 2021 22:28:22
' answered with 'corrected' (Site from DM).	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	12 Mar 2021 22:28:14
	(b) (4)	
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	04 Feb 2021 08:40:07
' (Site from DM).		
User entered 'No (N)'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'Supplement'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered '1'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered '26 Dec 2020'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered '0'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Jan 2021 21:30:50

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: LINEZOLID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 09:52:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 09:52:44
Data point term sent to Coder	System	08 Feb 2021 20:18:57
User entered 'Linezolid'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'Abscess'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered '600'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'twice daily (BID)'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered '6 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:48:06
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	14 Apr 2021 18:11:01
User entered 'No (N)' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	14 Apr 2021 18:10:16
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:36:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered '12 Feb 2021' reason for change: New Information	Diana Bahena (b) (4)	14 Apr 2021 18:10:16
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User entered '2'	System	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User entered '1'	System	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:52:07
User entered '804 (804)'	System	08 Feb 2021 20:18:25

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 22:00:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 22:00:42
Data point term sent to Coder	System	19 Apr 2021 21:59:39
User entered 'alprazolam'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'anxiety'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '0.5'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '01 Jan 2021'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '0'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 21:59:23

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:08:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 22:02:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 22:02:42
Data point term sent to Coder	System	19 Apr 2021 22:01:45
User entered 'buspirone'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'anxiety'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '5'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '01 Jan 2021'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '0'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 22:01:05

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 22:03:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 22:03:42
Data point term sent to Coder User entered 'losartan'	System Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:45 19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'hypertension'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '25'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '20 Feb 2021'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered '0'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:29
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:50:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 22:02:16

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:50:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	11 Jan 2021 23:33:37
User entered 'No (N)'	(b) (4) Karen Knapp (b) (4)	03 Sep 2020 14:53:12

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '24 Dec 2020'	Andrea Wendrow (b) (4)	11 Jan 2021 23:34:22

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Gastric sleeve surgery'	Andrea Wendrow (b) (4)	11 Jan 2021 23:34:22

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Adverse Event (AE)'	Andrea Wendrow (b) (4)	11 Jan 2021 23:34:22

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered empty.	Andrea Wendrow (b) (4)	11 Jan 2021 23:34:22

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '30 Jan 2021'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	08 Feb 2021 16:36:33

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'abscess drain'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	08 Feb 2021 16:36:33

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'Adverse Event (AE)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	08 Feb 2021 16:36:33

US3812132

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:09:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered empty.	(b) (4) Andrea Wendrow (b) (4) (b) (4)	08 Feb 2021 16:36:33

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'USA-US101-2021-MRNA-1273-P301000004'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Yes (Y)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Yes (Y)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Richard'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Novak'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '808 S. Wood St'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Chicago'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'IL'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '60612'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'US'	System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 13:51:19
Signature has been broken.	System	22 Feb 2021 17:52:16
User entered '2'	System	22 Feb 2021 17:52:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'USA-US101-2021-MRNA-1273-P301000004'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Yes (Y)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Yes (Y)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Richard'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Novak'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '808 S. Wood St'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Chicago'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'IL'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '60612'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'US'	System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 13:51:19
Signature has been broken.	System	22 Feb 2021 17:52:16
User entered '2'	System	22 Feb 2021 17:52:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:50:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '15/Jan/2021 09:31'	(b) (4) System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:50:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '1'	(b) (4), (b) (6)	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'USA-US101-2021-MRNA-1273-P301000004'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Yes (Y)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Yes (Y)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Richard'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Novak'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '808 S. Wood St'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Chicago'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'IL'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '60612'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'US'	System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 13:51:19
Signature has been broken.	System	22 Feb 2021 17:52:16
User entered '2'	System	22 Feb 2021 17:52:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:50:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered '22/Feb/2021 12:52'	(b) (4) System	22 Feb 2021 17:52:16

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:50:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:51:04
User entered '1'	(b) (4), (b) (6)	22 Feb 2021 17:52:16

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'USA-US101-2021-MRNA-1273-P301000004'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Yes (Y)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Yes (Y)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'No (N)'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Richard'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Novak'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '808 S. Wood St'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'Chicago'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'IL'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered '60612'	System	15 Jan 2021 14:30:42

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 14:32:04
User entered 'US'	System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 13:51:19
Signature has been broken.	System	22 Feb 2021 17:52:16
User entered '2'	System	22 Feb 2021 17:52:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	15 Jan 2021 14:31:34

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:50:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered '05/Mar/2021 08:51'	(b) (4) System	05 Mar 2021 13:51:19

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:50:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:27
User entered '1'	(b) (4), (b) (6)	05 Mar 2021 13:51:19

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'USA-US101-2021-MRNA-1273-P301000006'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Richard'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Novak'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '808 S. Wood St'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Chicago'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'IL'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '60612'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'US'	(b) (4) System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Apr 2021 15:17:31
User entered '3'	System	08 Mar 2021 15:46:03
User entered '2'	System	05 Mar 2021 16:28:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'USA-US101-2021-MRNA-1273-P301000006'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Richard'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Novak'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '808 S. Wood St'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Chicago'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'IL'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '60612'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'US'	(b) (4) System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Apr 2021 15:17:31
User entered '3'	System	08 Mar 2021 15:46:03
User entered '2'	System	05 Mar 2021 16:28:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:50:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '09/Feb/2021 08:28'	(b) (4) System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:50:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'USA-US101-2021-MRNA-1273-P301000006'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Richard'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Novak'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '808 S. Wood St'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Chicago'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'IL'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '60612'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'US'	(b) (4) System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Apr 2021 15:17:31
User entered '3'	System	08 Mar 2021 15:46:03
User entered '2'	System	05 Mar 2021 16:28:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:50:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '05/Mar/2021 11:28'	(b) (4) System	05 Mar 2021 16:28:22

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:50:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:27
User entered '1'	(b) (4), (b) (6)	05 Mar 2021 16:28:22

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'USA-US101-2021-MRNA-1273-P301000006'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Richard'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Novak'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '808 S. Wood St'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Chicago'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'IL'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '60612'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'US'	(b) (4) System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Apr 2021 15:17:31
User entered '3'	System	08 Mar 2021 15:46:03
User entered '2'	System	05 Mar 2021 16:28:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:50:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '08/Mar/2021 10:45'	(b) (4) System	08 Mar 2021 15:46:03

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:50:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 15:17:19
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:58:24
User entered '1'	(b) (4), (b) (6)	08 Mar 2021 15:46:03

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'USA-US101-2021-MRNA-1273-P301000006'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'No (N)'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Richard'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Novak'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '808 S. Wood St'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'Chicago'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered 'IL'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:59
User entered '60612'	System	09 Feb 2021 13:27:44

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:50:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
User entered 'US'	(b) (4) System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Apr 2021 15:17:31
User entered '3'	System	08 Mar 2021 15:46:03
User entered '2'	System	05 Mar 2021 16:28:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:39:56
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:28:06

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:50:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:24:28
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User entered '23/Apr/2021 10:17'	(b) (4) System	23 Apr 2021 15:17:31

US3812132

Folder: SAE USA-US101-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:50:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:24:28
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:36:56
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 15:17:31