

US3822443 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:57:16

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US3822443

Form: Participant Creation

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

[Participant ID](#)

US3822443

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

US3822443

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 SEP 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) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
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) 08 Mar 2021 13:19:15

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Date of Informed Consent (dd MMM yyyy)	28 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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) 08 Mar 2021 13:19:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 08 Mar 2021 13:19:16

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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) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	NEARSIGHTED
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 (3)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	SHORTNESS OF BREATH RELATED TO COPD
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	PNEUMONIA
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	CHEST DISCOMFORT
Start date (dd MMM yyyy)	UN JUN 2020
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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	ATRIAL FIBILLILATION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	HEARTBURN
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 (13)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	INDIGESTION
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 (14)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	FREQUENT CONSTIPATION
Start date (dd MMM yyyy)	UN MAR 2020
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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	ULCERS - GI HEMMORHAGE
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	ACID REFLUX
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 (17)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN MAR 2020
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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	URINARY INCONTINENCE
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 (19)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	OVERACTIVE BLADDER
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 (20)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	HERNIATED DISC
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	OSTEOPOROSIS
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)	
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 (22)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	BACK SURGERY FOR HERNIATED DISC
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

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

US3822443

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:45
Height (xxx.x)	66 in
Weight (xxx.x)	121.6 lb
BMI (xxx.x)	19.66779 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822443

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 08 Mar 2021 13:19:15

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Date of assessment (dd MMM yyyy) 28 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1976

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Mar 2021 13:19:16

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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	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 SEP 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) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

What was the date of randomization? (dd MMM yyyy) 28 SEP 2020

What was the participant's randomization number? 191260

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

>=18 and <65 years and at risk ☐

>=65 years ☒

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

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

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

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

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

Liver Disease Yes ☐
No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐
No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

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) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

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)	28 SEP 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

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)	28 SEP 2020
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:13
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	48 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

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) 08 Mar 2021 13:19:16

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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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 11:31 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:31

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	11:03 (24 HR)
Collection date and time (derived)	28 SEP 2020 11:03

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:10	28 SEP 2020 11:10
Nasopharyngeal Swab 2	No		

US3822443

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

28 SEP 2020 12:01

PC Open Date & Time

28 SEP 2020 11:51

PC Close Date & Time

28 SEP 2020 14:21

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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.

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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 95.6 °F

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

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

PC Time Stamp	29 SEP 2020 09:24
PC Open Date & Time	28 SEP 2020 15:16
PC Close Date & Time	29 SEP 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

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

93.2 °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

30 SEP 2020 10:29

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

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

96.8 °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

30 SEP 2020 19:28

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

95.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:25

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 13:38

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

03 OCT 2020 13:56

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

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

95.9 °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

04 OCT 2020 15:00

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

28 SEP 2020 12:02

PC Open Date & Time

28 SEP 2020 11:51

PC Close Date & Time

28 SEP 2020 14:21

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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

29 SEP 2020 09:26

PC Open Date & Time

28 SEP 2020 15:16

PC Close Date & Time

29 SEP 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 10:30

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 19:29

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

01 OCT 2020 12:26

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

02 OCT 2020 13:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

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

03 OCT 2020 13:57

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

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

04 OCT 2020 15:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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 ☐

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 12:03
PC Open Date & Time	28 SEP 2020 11:51
PC Close Date & Time	28 SEP 2020 14:21

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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 ☐

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 09:27
PC Open Date & Time	28 SEP 2020 15:16
PC Close Date & Time	29 SEP 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

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)

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	30 SEP 2020 10:31
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

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)

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	30 SEP 2020 19:30
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

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EAB) (1725)

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	01 OCT 2020 12:27
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

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)

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US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	02 OCT 2020 13:40
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

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 ☒

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EAB) (1725)

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	03 OCT 2020 13:58
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

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 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	04 OCT 2020 15:02
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 05 OCT 2020 18:46

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3822443

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 OCT 2020 18:46
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3822443

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822443

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822443

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822443

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 08:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 10:10
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3822443

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

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.

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

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) 27 OCT 2020

What was the treatment time? (00:00-23:59) 09:40 (24 HR)

Treatment Date and Time (derived) 27 OCT 2020 09:40

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

US3822443

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

09:04 (24 HR)

Collection date and time (derived)

27 OCT 2020 09:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Collection date (dd MMM yyyy)			27 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:10	27 OCT 2020 09:10
Nasopharyngeal Swab 2	No		

US3822443

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

98.6 °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

27 OCT 2020 10:09

PC Open Date & Time

27 OCT 2020 10:00

PC Close Date & Time

27 OCT 2020 12:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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	27 OCT 2020 17:41
PC Open Date & Time	27 OCT 2020 13:25
PC Close Date & Time	28 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 OCT 2020 12:39

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 14:15

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

96.9 °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

30 OCT 2020 12:55

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 OCT 2020 14:14

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 15:12

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 18:32

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

27 OCT 2020 10:09

PC Open Date & Time

27 OCT 2020 10:00

PC Close Date & Time

27 OCT 2020 12:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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

27 OCT 2020 17:41

PC Open Date & Time

27 OCT 2020 13:25

PC Close Date & Time

28 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 12:40

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 3

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

29 OCT 2020 14:16

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

30 OCT 2020 12:56

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

31 OCT 2020 14:15

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

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

01 NOV 2020 15:13

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

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

02 NOV 2020 18:33

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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 ☐

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 10:11
PC Open Date & Time	27 OCT 2020 10:00
PC Close Date & Time	27 OCT 2020 12:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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 ☐

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 17:42
PC Open Date & Time	27 OCT 2020 13:25
PC Close Date & Time	28 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	28 OCT 2020 12:41
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	29 OCT 2020 14:17
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

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)

118 of 2192

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	30 OCT 2020 12:57
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

120 of 2192

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	31 OCT 2020 14:16
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

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 ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	01 NOV 2020 15:13
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

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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US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

Yes ☐	
PC Time stamp	02 NOV 2020 18:34
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3822443

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822443

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822443

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822443

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 13:19:22

Generated On: 10 Jun 2021 09:57:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 13:19:22

Generated On: 10 Jun 2021 09:57:16

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 09:55
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822443

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 13:19:22

Generated On: 10 Jun 2021 09:57:16

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.

US3822443

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 13:19:22

Generated On: 10 Jun 2021 09:57:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 NOV 2020

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

23 NOV 2020 09:55

US3822443

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:16

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT	DAY 61
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 17:27:57
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT	DAY 68
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	02 DEC 2020 20:23:29
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 10:10:19

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 08:32:30

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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	23 DEC 2020 08:31:41
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 13:40:26
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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 ☐
Have 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	06 JAN 2021 09:48:38
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

13 JAN 2021 17:26:09

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

20 JAN 2021 07:02:36

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

27 JAN 2021 09:54:54

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

03 FEB 2021 12:35:15

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3822443

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:57:16

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

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Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822443

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822443

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822443

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3822443

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:57:16

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 ☐

US3822443

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:57:16

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3822443

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

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	14 JAN 2021

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

Folder OID	UNBLND_DECIDE

US3822443

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 06:31:36

Generated On: 10 Jun 2021 09:57:16

Date of updated informed consent (dd MMM yyyy) 14 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 13 JAN 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 _____

US3822443

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

14:26 (24 HR)

Collection date and time (derived)

14 JAN 2021 14:26

US3822443

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	14:37
Collection Date and Time (derived)	14 JAN 2021 14:37

US3822443

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

AEID	
Adverse event	ARM PAIN
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)	14 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	15 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 (1)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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AEID	USA-US126-2020-MRNA-1273-P30 1000012
Adverse event	ABDOMINAL PAIN
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)	04 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)	14 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)	04 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	14 DEC 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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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	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 (2)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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THE SUBJECT WAS
EXPERIENCING NAUSEA AND
VOMITING AND PRESENTED TO
THE EMERGENCY
DEPARTMENT. SHE WAS
ADMITTED FOR EVALUATION
AND WAS DISCHARGED 10
DAYS LATER IN STABLE
CONDITION.

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 (3)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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AEID

Adverse event

SWOLLEN FEET

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)

02 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)

08 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____ _____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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AEID USA-US126-2021-MRNA-1273-P30
1000005

Adverse event RIGHT LOWER LOBE
PULMONARY NODULE
CONCERNING FOR PRIMARY
LUNG MALIGNANCY

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) 11 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) 11 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 True

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 ☐

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Folder: Adverse Events

Form: Adverse Events (4)

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	No	☐
	Unknown	☐
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	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		

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

THE SUBJECT'S SPOUSE
CALLED TO REPORT THAT THE
SUBJECT EXPIRED ON
11-FEB-2021. THE CAUSE OF
DEATH IS LIKELY THE
SUBJECT'S RECENT DIAGNOSIS
OF POSSIBLE RIGHT LOWER
LOBE PULMONARY NODULE
CONCERNING FOR PRIMARY
LUNG MALIGNANCY. RECORDS
WILL BE REQUESTED.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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Name of Medication BUDESONIDE

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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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 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 (2)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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Name of Medication GIGOXIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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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 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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Name of Medication DILTIAZEM

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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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 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 (4)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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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 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)	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 (5)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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Name of Medication IPRATROPIUM BROMIDE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 42

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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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 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)	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 (6)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication LEVALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 0.63

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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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 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)	_____	
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 (7)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication LINZESS

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 72

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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 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 (8)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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 FEB 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication SHORTNESS OF BREATH, COPD

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

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 (10)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication	PERFOROMIST
Prophylaxis	Yes ☐ No ☒
Indication	COPD
Dose per administration	20
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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) _____		
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 (12)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COPD

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) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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) _____		
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 (13)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication PROLIA

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 MONTHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication PROVENTIL

Prophylaxis Yes ☐
No ☒

Indication COPD, SHORTNESS OF BREATH

Dose per administration 90

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

EVERY 4 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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 2010
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) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication	YUPELRI
Prophylaxis	Yes ☐ No ☒
Indication	COPD
Dose per administration	175
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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 JAN 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 (16)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication MUCINEX DM

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication CENTRUM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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	☒

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication VITAMIN E

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 450

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 (18)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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) _____		
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) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 5000

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) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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) _____		
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) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication CALTRATE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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) _____		
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 (21)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication COD LIVER OIL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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) _____		
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	☒

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 81

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 (22)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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	☒

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication TDAP

Prophylaxis Yes ☒
No ☐

Indication VACCINE

Dose per administration UNK

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 (23)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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)	28 MAY 2014	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		28 MAY 2014
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	☐

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication INFLUENZA

Prophylaxis Yes ☒
No ☐

Indication VACCINE

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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)		15 OCT 2019
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2019
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	☐

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication PNEUMOCOCCAL

Prophylaxis Yes ☒
No ☐

Indication VACCINE

Dose per administration UNK

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) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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)	14 APR 2016	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 APR 2016
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 (26)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN AND
SWOLLEN FEET

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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)	4 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	5 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	☒

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN

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 (27)

Data signed: (b) (4) 08 Mar 2021 13:19:13

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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)	12 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	12 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 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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 (28)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 2

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

If dose unit is Other, specify LITERS

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 (29)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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)	4 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 45

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 (30)

Data signed: (b) (4) 08 Mar 2021 13:19:13

Generated On: 10 Jun 2021 09:57:16

	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)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	19 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	☒

US3822443

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 10 Jun 2021 09:57:16

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify

US3822443

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 23 Apr 2021 14:47:48

Generated On: 10 Jun 2021 09:57:16

Date of study discontinuation/completion (dd MMM yyyy) 11 FEB 2021

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) 11 FEB 2021

Was autopsy performed?

Yes	☐
No	☒
Unknown	☐

US3822443

Folder: SAE-USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

SAEID	USA-US126-2020-MRNA-1273-P301000012
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	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

SAEID	USA-US126-2020-MRNA-1273-P301000012
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	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	28/DEC/2020 05:45
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

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

SAEID	USA-US126-2020-MRNA-1273-P301000012
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	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/JAN/2021 17:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Mar 2021 13:19:15

Generated On: 10 Jun 2021 09:57:16

SAEID	USA-US126-2020-MRNA-1273-P301000012
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	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	27/JAN/2021 10:35
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

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 17:40:28

Generated On: 10 Jun 2021 09:57:16

SAEID	USA-US126-2021-MRNA-1273-P301000005
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	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 17:40:28

Generated On: 10 Jun 2021 09:57:16

SAEID	USA-US126-2021-MRNA-1273-P301000005
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	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/FEB/2021 11:17
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

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 17:40:28

Generated On: 10 Jun 2021 09:57:16

SAEID	USA-US126-2021-MRNA-1273-P301000005
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	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	19/FEB/2021 12:24
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

US3822443 (Prod: Tryon Medical Partners, PLLC)

US3822443

Form: Participant Creation

Generated On: 10 Jun 2021 09:57:16

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'US3822443'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 14:47:47

US3822443

Form: Participant Creation

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:17:50

US3822443

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 14:47:48

US3822443

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:17:50

US3822443

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'SCRN'	System	04 Oct 2020 13:17:50

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered (b) (6) 1945'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 14:47:50

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '75'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'YEARS'	System	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '75'	System	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:09

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'Sep 2020'	System	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2020'	System	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:31

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 14:47:48

US3822443

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	28 Sep 2020 15:44:37

US3822443

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:37

US3822443

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:57:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:23:28

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:24:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:24:45
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:24:26
User entered 'Seasonal allergies'	(b) (4), (b) (6)	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2010'	System	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:23:48

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:24:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:24:46
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:24:27
User entered 'Nearsighted'	(b) (4), (b) (6)	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '1990'	System	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:24:16

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Dec 2020 16:25:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:25:48
Data point term sent to Coder	System	02 Dec 2020 16:25:28
User entered 'Sinus infections'	(b) (4), (b) (6)	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2010'	System	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:25:23

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Dysphagia, LLT: Swallowing difficult - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:27:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:27:54
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:26:31
User entered 'Trouble swallowing'	(b) (4), (b) (6)	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2010'	System	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:25:57

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:28:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:28:57
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:27:31
User entered 'COPD'	(b) (4), (b) (6)	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2006'	System	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:26:38

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 07:49:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 07:49:55
Data point term sent to Coder	System	02 Dec 2020 16:27:32
User entered 'Shortness of breath related to COPD'	(b) (4), (b) (6)	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2006'	System	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:26:56

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:28:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:28:57
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:27:33
User entered 'Pneumonia'	(b) (4), (b) (6)	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2008'	System	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2012'	System	02 Dec 2020 16:27:15

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

Condition

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per CDM CR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST DISCOMFORT is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:18:51
Query 'Per CDM CR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST DISCOMFORT is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. ' answered with 'patient is deceased. I cannot answer this query.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:53:41
User opened query 'Per CDM CR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST DISCOMFORT is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:37:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest discomfort - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:29:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:29:45
Data point term sent to Coder	System	02 Dec 2020 16:28:33
User entered 'Chest Discomfort'	(b) (4), (b) (6)	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:27:37

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
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)	02 Dec 2020 16:29:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:29:45
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:28:34
User entered 'Hypertension'	(b) (4), (b) (6)	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2016'	System	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:27:47

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Dec 2020 07:46:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 07:46:11
Data point term sent to Coder	System	02 Dec 2020 16:28:35
User entered 'Atrial Fibillilation'	(b) (4), (b) (6)	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2014' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:27:57
User entered 'un UNK 2017'	(b) (4), (b) (6)	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	29 Jan 2021 14:27:57
User entered 'Jan 2017'	System	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2014'	System	29 Jan 2021 14:27:57
User entered '2017'	System	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:28:02

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
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)	02 Dec 2020 16:29:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:29:45
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:28:35
User entered 'Anxiety'	(b) (4), (b) (6)	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2014'	System	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:28:26

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Dec 2020 16:30:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:30:46
Data point term sent to Coder	System	02 Dec 2020 16:29:36
User entered 'Heartburn'	(b) (4), (b) (6)	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2015'	System	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:28:36

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Indigestion - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Dec 2020 16:30:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:30:46
Data point term sent to Coder	System	02 Dec 2020 16:29:36
User entered 'Indigestion'	(b) (4), (b) (6)	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2015'	System	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:28:57

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:30:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:30:46
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:29:36
User entered 'Frequent constipation'	(b) (4), (b) (6)	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un Mar 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Mar 2020'	System	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:29:20

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

Condition

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastrointestinal ulcers and perforation, site unspecified, PT: Gastrointestinal ulcer haemorrhage, LLT: Gastrointestinal ulcer hemorrhage - version MedDRA\23.0.	Coder Import (b) (4)	03 Dec 2020 07:53:05
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Dec 2020 07:53:05
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:30:38
User entered 'Ulcers - GI Hemorrhage'	(b) (4), (b) (6)	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2015'	System	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2015'	System	02 Dec 2020 16:29:45

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:31:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:31:47
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:30:38
User entered 'Acid reflux'	(b) (4), (b) (6)	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2015'	System	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:30:04

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Dec 2020 16:31:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:31:48
Data point term sent to Coder	System	02 Dec 2020 16:30:38
User entered 'Irritable bowel syndrome'	(b) (4), (b) (6)	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un Mar 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Mar 2020'	System	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:30:21

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:31:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:31:48
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:30:38
User entered 'Urinary Incontinence'	(b) (4), (b) (6)	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2019'	System	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:30:38

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\23.0.	Coder Import (b) (4)	02 Dec 2020 16:32:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Dec 2020 16:32:46
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:31:39
User entered 'Overactive bladder'	(b) (4), (b) (6)	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2019'	System	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:30:59

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:32:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:32:45
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:31:39
User entered 'Herniated disc'	(b) (4), (b) (6)	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 1997'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '1997'	System	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2014'	System	02 Dec 2020 16:31:19

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:32:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:32:46
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:31:39
User entered 'Osteoporosis'	(b) (4), (b) (6)	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:31:32

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 10:39:04
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:38:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Intervertebral disc operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 07:48:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 07:48:20
Data point term sent to Coder	System	02 Dec 2020 16:32:40
User entered 'Back surgery for herniated disc'	(b) (4), (b) (6)	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2014'	System	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:39:12
User entered empty.	System	02 Dec 2020 16:31:48

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Bleeding tendencies, PT: Increased tendency to bruise, LLT: Increased tendency to bruise - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:33:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:33:48
	(b) (4)	
Data point term sent to Coder System	System	02 Dec 2020 16:32:40
User entered 'Easy bruising'	(b) (4), (b) (6)	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:32:09

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:33:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 16:33:48
	(b) (4)	
Data point term sent to Coder	System	02 Dec 2020 16:32:40
User entered 'Tubal ligation'	(b) (4), (b) (6)	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 1976'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered 'Jan 1976'	System	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered '1976'	System	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:39:53
User entered empty.	System	02 Dec 2020 16:32:21

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per CDM: Per pages 16-17 of CCGs (2.0) please complete "Were vital sings assessed?", "Date of assessment" and "Time of assessment". Please review and update correctly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:11:30
Query 'Per CDM: Per pages 16-17 of CCGs (2.0) please complete "Were vital sings assessed?", "Date of assessment" and "Time of assessment". Please review and update correctly. Thank you.' answered with 'updated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:09:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:09:15
User opened query 'Per CDM: Per pages 16-17 of CCGs (2.0) please complete "Were vital sings assessed?", "Date of assessment" and "Time of assessment". Please review and update correctly. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:58:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 13:58:55
Query 'Data is required. Please complete.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	04 Oct 2020 13:18:36
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Oct 2020 13:18:31
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4)	27 Oct 2020 21:09:15
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '09:45' reason for change: Data Entry Error	(b) (4)	27 Oct 2020 21:09:15
User entered empty.	Krishna Shah (b) (4)	04 Oct 2020 13:18:31
	(b) (4), (b) (6)	

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '28 Sep 2020 09:45'	System	27 Oct 2020 21:09:15
User entered empty.	System	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '66' in	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31
DataPoint set to visible.	System	28 Sep 2020 15:44:37

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '121.6' lb	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31
DataPoint set to visible.	System	28 Sep 2020 15:44:37

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '19.66779'	System	04 Oct 2020 13:18:31
DataPoint set to visible.	System	28 Sep 2020 15:44:37

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'kg/m2'	System	04 Oct 2020 13:18:31
DataPoint set to visible.	System	28 Sep 2020 15:44:37

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'bpm'	System	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'breaths/min'	System	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	04 Oct 2020 13:18:31

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:45

US3822443

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:18:45

US3822443

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:57:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:08

US3822443

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:57:16

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:08

US3822443

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:57:16

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per CDM: "If No, what is the reason" is "Surgically sterile"; however the procedure is not recorded in "Medical History" form. Please refer to pages 22-23 of CCGs version 2.0, and update all relevant medical procedures in "Medical History" form. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 11:25:31
Query 'Per CDM: "If No, what is the reason" is "Surgically sterile"; however the procedure is not recorded in "Medical History" form. Please refer to pages 22-23 of CCGs version 2.0, and update all relevant medical procedures in "Medical History" form. Thank you.	(b) (4), (b) (6)	02 Dec 2020 16:40:05
' answered with 'added' (Site from DM). User opened query 'Per CDM: "If No, what is the reason" is "Surgically sterile"; however the procedure is not recorded in "Medical History" form. Please refer to pages 22-23 of CCGs version 2.0, and update all relevant medical procedures in "Medical History" form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:37:13
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	04 Oct 2020 13:19:08

US3822443

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:57:16

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:08

US3822443

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:57:16

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 1976'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:08

US3822443

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:57:16

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:08

US3822443

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:08

US3822443

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:57:16

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:08

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:19:26

US3822443

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:50

US3822443

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:50

US3822443

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:44:50

US3822443

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'VISIT1'	System	28 Sep 2020 15:44:50

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 14:47:54

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '191260'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 14:47:54

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 14:47:54

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:57:15

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:57:15

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:57:15

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:57:15

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:57:15

US3822443

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:16

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:57:15
DataPoint set to visible.	System	28 Sep 2020 15:44:31

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' (Site from DM). Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' answered with 'updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 07:03:54
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:09:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:09:46
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:48:22
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	27 Oct 2020 21:09:46
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' (Site from DM). Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' answered with 'updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 07:03:54
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:09:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:09:46
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:48:22
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 13:20:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	27 Oct 2020 21:09:46
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '10:55'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '28 Sep 2020 10:55'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '80'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'bpm'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'breaths/min'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '120'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '70'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' (Site from DM). Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' answered with 'updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 07:03:54
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:09:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:09:46
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update 'ND' accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:48:22
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	27 Oct 2020 21:09:46
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '12:13'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '28 Sep 2020 12:13'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '78'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'bpm'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '20'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'breaths/min'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '111'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 11:24:42
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	04 Oct 2020 13:20:57
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		04 Oct 2020 13:20:42
User entered '48'	(b) (4), (b) (6)	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	04 Oct 2020 13:20:42

US3822443

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:07

US3822443

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:07

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '11:31'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '28 Sep 2020 11:31'	System	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'ONCE'	System	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 15:45:13

US3822443

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:22

US3822443

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:22

US3822443

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '11:03'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:22

US3822443

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '28 Sep 2020 11:03'	System	04 Oct 2020 13:21:22

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:57:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '11:10'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '28 Sep 2020 11:10'	System	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	04 Oct 2020 13:21:34

US3822443

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 13:21:38

US3822443

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	04 Oct 2020 13:21:38

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T11:59:35', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c41d5876-9543-4189-a211-94f2977c9a29'	System	28 Sep 2020 16:02:01
User entered 'Yes (Y)'	System	28 Sep 2020 16:02:01

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:00:38', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c41d5876-9543-4189-a211-94f2977c9a29' User entered '97.1'	System	28 Sep 2020 16:02:01
	System	28 Sep 2020 16:02:01

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:00:47', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c41d5876-9543-4189-a211-94f2977c9a29'	System	28 Sep 2020 16:02:01
User entered 'No (N)'	System	28 Sep 2020 16:02:01

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:01:15', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c41d5876-9543-4189-a211-94f2977c9a29'	System	28 Sep 2020 16:02:01
User entered '28 Sep 2020 12:01'	System	28 Sep 2020 16:02:01

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 11:51'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 14:21'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:23:37', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '622018d6-d73a-4bed-9377-21041bd17967'	System	29 Sep 2020 13:24:48
User entered 'Yes (Y)'	System	29 Sep 2020 13:24:48

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:23:51', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '622018d6-d73a-4bed-9377-21041bd17967'	System	29 Sep 2020 13:24:48
User entered '95.6'	System	29 Sep 2020 13:24:48

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:24:04', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '622018d6-d73a-4bed-9377-21041bd17967'	System	29 Sep 2020 13:24:48
User entered 'No (N)'	System	29 Sep 2020 13:24:48

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:24:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '622018d6-d73a-4bed-9377-21041bd17967'	System	29 Sep 2020 13:24:48
User entered '29 Sep 2020 09:24'	System	29 Sep 2020 13:24:48

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 15:16'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 2'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:29:05', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '9c549530-dc4e-44a1-93e1-773c82c825a8'	System	30 Sep 2020 14:29:34
User entered 'Yes (Y)'	System	30 Sep 2020 14:29:34

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:29:16', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '9c549530-dc4e-44a1-93e1-773c82c825a8'	System	30 Sep 2020 14:29:34
User entered '93.2'	System	30 Sep 2020 14:29:34

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:29:21', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '9c549530-dc4e-44a1-93e1-773c82c825a8'	System	30 Sep 2020 14:29:34
User entered 'No (N)'	System	30 Sep 2020 14:29:34

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:29:31', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '9c549530-dc4e-44a1-93e1-773c82c825a8'	System	30 Sep 2020 14:29:34
User entered '30 Sep 2020 10:29'	System	30 Sep 2020 14:29:34

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 3'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:28:01', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '0438ac89-00b3-4ead-b62f-cfa6d255c25f' User entered 'Yes (Y)'	System	30 Sep 2020 23:28:44
	System	30 Sep 2020 23:28:44

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:28:14', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '0438ac89-00b3-4ead-b62f-cfa6d255c25f' User entered '96.8'	System	30 Sep 2020 23:28:44
	System	30 Sep 2020 23:28:44

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:28:21', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '0438ac89-00b3-4ead-b62f-cfa6d255c25f'	System	30 Sep 2020 23:28:44
User entered 'No (N)'	System	30 Sep 2020 23:28:44

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:28:41', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '0438ac89-00b3-4ead-b62f-cfa6d255c25f' User entered '30 Sep 2020 19:28'	System	30 Sep 2020 23:28:44
	System	30 Sep 2020 23:28:44

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 4'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:24:45', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'bdf53d5d-cf03-4b3f-8837-140cfd3bca33'	System	01 Oct 2020 16:25:40
User entered 'Yes (Y)'	System	01 Oct 2020 16:25:40

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:25:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'bdf53d5d-cf03-4b3f-8837-140cfd3bca33'	System	01 Oct 2020 16:25:40
User entered '95.0'	System	01 Oct 2020 16:25:40

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:25:31', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'bdf53d5d-cf03-4b3f-8837-140cfd3bca33'	System	01 Oct 2020 16:25:40
User entered 'No (N)'	System	01 Oct 2020 16:25:40

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:25:35', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'bdf53d5d-cf03-4b3f-8837-140cfd3bca33'	System	01 Oct 2020 16:25:40
User entered '01 Oct 2020 12:25'	System	01 Oct 2020 16:25:40

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 5'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:38:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8147fd5f-6578-4845-9424-1d4e17e23058'	System	02 Oct 2020 17:39:03
User entered 'Yes (Y)'	System	02 Oct 2020 17:39:03

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:38:40', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8147fd5f-6578-4845-9424-1d4e17e23058'	System	02 Oct 2020 17:39:03
User entered '98.0'	System	02 Oct 2020 17:39:03

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:38:45', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8147fd5f-6578-4845-9424-1d4e17e23058'	System	02 Oct 2020 17:39:03
User entered 'No (N)'	System	02 Oct 2020 17:39:03

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:38:57', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8147fd5f-6578-4845-9424-1d4e17e23058'	System	02 Oct 2020 17:39:03
User entered '02 Oct 2020 13:38'	System	02 Oct 2020 17:39:03

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 6'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:56:26', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60da8e3b-4d3d-4ac2-997b-899a76ac7901'	System	03 Oct 2020 17:57:01
User entered 'Yes (Y)'	System	03 Oct 2020 17:57:01

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:56:39', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60da8e3b-4d3d-4ac2-997b-899a76ac7901'	System	03 Oct 2020 17:57:01
User entered '97.9'	System	03 Oct 2020 17:57:01

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:56:46', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60da8e3b-4d3d-4ac2-997b-899a76ac7901'	System	03 Oct 2020 17:57:01
User entered 'No (N)'	System	03 Oct 2020 17:57:01

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:56:55', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60da8e3b-4d3d-4ac2-997b-899a76ac7901'	System	03 Oct 2020 17:57:01
User entered '03 Oct 2020 13:56'	System	03 Oct 2020 17:57:01

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 7'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T14:59:47', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'cae47618-6cfe-493c-b971-0d21126600d4'	System	04 Oct 2020 19:00:19
User entered 'Yes (Y)'	System	04 Oct 2020 19:00:19

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T14:59:58', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'cae47618-6cfe-493c-b971-0d21126600d4'	System	04 Oct 2020 19:00:19
User entered '95.9'	System	04 Oct 2020 19:00:19

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:00:12', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'cae47618-6cfe-493c-b971-0d21126600d4'	System	04 Oct 2020 19:00:19
User entered 'No (N)'	System	04 Oct 2020 19:00:19

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:00:16', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'cae47618-6cfe-493c-b971-0d21126600d4'	System	04 Oct 2020 19:00:19
User entered '04 Oct 2020 15:00'	System	04 Oct 2020 19:00:19

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:01:40', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69ec67a1-9e57-4140-ba88-92de8134426e'	System	28 Sep 2020 16:03:22
User entered 'None (1)'	System	28 Sep 2020 16:03:22

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:01:45', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69ec67a1-9e57-4140-ba88-92de8134426e' User entered 'No (N)'	System	28 Sep 2020 16:03:22
	System	28 Sep 2020 16:03:22

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:01:53', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69ec67a1-9e57-4140-ba88-92de8134426e'	System	28 Sep 2020 16:03:22
User entered 'No (N)'	System	28 Sep 2020 16:03:22

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:02:08', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69ec67a1-9e57-4140-ba88-92de8134426e'	System	28 Sep 2020 16:03:22
User entered 'None (1)'	System	28 Sep 2020 16:03:22

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:02:20', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69ec67a1-9e57-4140-ba88-92de8134426e'	System	28 Sep 2020 16:03:22
User entered '28 Sep 2020 12:02'	System	28 Sep 2020 16:03:22

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 11:51'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 14:21'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:25:06', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f403a4af-52c8-40e7-9f59-16e79ee3bee1'	System	29 Sep 2020 13:26:11
User entered 'None (1)'	System	29 Sep 2020 13:26:11

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:25:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f403a4af-52c8-40e7-9f59-16e79ee3bee1'	System	29 Sep 2020 13:26:11
User entered 'No (N)'	System	29 Sep 2020 13:26:11

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:25:27', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f403a4af-52c8-40e7-9f59-16e79ee3bee1'	System	29 Sep 2020 13:26:11
User entered 'No (N)'	System	29 Sep 2020 13:26:11

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:25:44', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f403a4af-52c8-40e7-9f59-16e79ee3bee1'	System	29 Sep 2020 13:26:11
User entered 'None (1)'	System	29 Sep 2020 13:26:11

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:26:08', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f403a4af-52c8-40e7-9f59-16e79ee3bee1'	System	29 Sep 2020 13:26:11
User entered '29 Sep 2020 09:26'	System	29 Sep 2020 13:26:11

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 15:16'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 2'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:29:56', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'dab88c44-3607-40f6-8fc3-e8e63c169fd1'	System	30 Sep 2020 14:30:57
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 14:30:57

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:30:01', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'dab88c44-3607-40f6-8fc3-e8e63c169fd1'	System	30 Sep 2020 14:30:57
User entered 'No (N)'	System	30 Sep 2020 14:30:57

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:30:13', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'dab88c44-3607-40f6-8fc3-e8e63c169fd1'	System	30 Sep 2020 14:30:57
User entered 'No (N)'	System	30 Sep 2020 14:30:57

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:30:24', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'dab88c44-3607-40f6-8fc3-e8e63c169fd1'	System	30 Sep 2020 14:30:57
User entered 'None (1)'	System	30 Sep 2020 14:30:57

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:30:51', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'dab88c44-3607-40f6-8fc3-e8e63c169fd1'	System	30 Sep 2020 14:30:57
User entered '30 Sep 2020 10:30'	System	30 Sep 2020 14:30:57

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 3'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:29:03', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '25f70c37-303e-4197-89a8-d05bbb3a4267'	System	30 Sep 2020 23:29:48
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 23:29:48

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:29:08', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '25f70c37-303e-4197-89a8-d05bbb3a4267'	System	30 Sep 2020 23:29:48
User entered 'No (N)'	System	30 Sep 2020 23:29:48

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:29:36', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '25f70c37-303e-4197-89a8-d05bbb3a4267'	System	30 Sep 2020 23:29:48
User entered 'No (N)'	System	30 Sep 2020 23:29:48

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:29:17', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '25f70c37-303e-4197-89a8-d05bbb3a4267'	System	30 Sep 2020 23:29:48
User entered 'None (1)'	System	30 Sep 2020 23:29:48

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:29:44', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '25f70c37-303e-4197-89a8-d05bbb3a4267'	System	30 Sep 2020 23:29:48
User entered '30 Sep 2020 19:29'	System	30 Sep 2020 23:29:48

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 4'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:25:51', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '382669cb-605e-45a8-a2ef-4166b9756c86'	System	01 Oct 2020 16:26:19
User entered 'None (1)'	System	01 Oct 2020 16:26:19

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:25:48', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '382669cb-605e-45a8-a2ef-4166b9756c86'	System	01 Oct 2020 16:26:19
User entered 'No (N)'	System	01 Oct 2020 16:26:19

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:25:56', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '382669cb-605e-45a8-a2ef-4166b9756c86'	System	01 Oct 2020 16:26:19
User entered 'No (N)'	System	01 Oct 2020 16:26:19

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:26:00', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '382669cb-605e-45a8-a2ef-4166b9756c86'	System	01 Oct 2020 16:26:19
User entered 'None (1)'	System	01 Oct 2020 16:26:19

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:26:14', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '382669cb-605e-45a8-a2ef-4166b9756c86'	System	01 Oct 2020 16:26:19
User entered '01 Oct 2020 12:26'	System	01 Oct 2020 16:26:19

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 5'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:06', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '91411f5c-5f80-4488-a9c4-1025c0ca420f'	System	02 Oct 2020 17:39:36
User entered 'None (1)'	System	02 Oct 2020 17:39:36

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '91411f5c-5f80-4488-a9c4-1025c0ca420f'	System	02 Oct 2020 17:39:36
User entered 'No (N)'	System	02 Oct 2020 17:39:36

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '91411f5c-5f80-4488-a9c4-1025c0ca420f'	System	02 Oct 2020 17:39:36
User entered 'No (N)'	System	02 Oct 2020 17:39:36

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:24', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '91411f5c-5f80-4488-a9c4-1025c0ca420f'	System	02 Oct 2020 17:39:36
User entered 'None (1)'	System	02 Oct 2020 17:39:36

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:30', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '91411f5c-5f80-4488-a9c4-1025c0ca420f' User entered '02 Oct 2020 13:39'	System	02 Oct 2020 17:39:36
	System	02 Oct 2020 17:39:36

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 6'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:03', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'b3163e9a-438e-4b87-9bac-27b5fc0d8c5e'	System	03 Oct 2020 17:57:31
User entered 'None (1)'	System	03 Oct 2020 17:57:31

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'b3163e9a-438e-4b87-9bac-27b5fc0d8c5e'	System	03 Oct 2020 17:57:31
User entered 'No (N)'	System	03 Oct 2020 17:57:31

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:12', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'b3163e9a-438e-4b87-9bac-27b5fc0d8c5e'	System	03 Oct 2020 17:57:31
User entered 'No (N)'	System	03 Oct 2020 17:57:31

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:17', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'b3163e9a-438e-4b87-9bac-27b5fc0d8c5e'	System	03 Oct 2020 17:57:31
User entered 'None (1)'	System	03 Oct 2020 17:57:31

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:27', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'b3163e9a-438e-4b87-9bac-27b5fc0d8c5e'	System	03 Oct 2020 17:57:31
User entered '03 Oct 2020 13:57'	System	03 Oct 2020 17:57:31

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 7'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:00:24', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '801d2d47-da98-45ba-bb41-2f2c89b2d1ee'	System	04 Oct 2020 19:01:24
User entered 'None (1)'	System	04 Oct 2020 19:01:24

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:00:28', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '801d2d47-da98-45ba-bb41-2f2c89b2d1ee'	System	04 Oct 2020 19:01:24
User entered 'No (N)'	System	04 Oct 2020 19:01:24

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:00:54', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '801d2d47-da98-45ba-bb41-2f2c89b2d1ee'	System	04 Oct 2020 19:01:24
User entered 'No (N)'	System	04 Oct 2020 19:01:24

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:00:58', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '801d2d47-da98-45ba-bb41-2f2c89b2d1ee'	System	04 Oct 2020 19:01:24
User entered 'None (1)'	System	04 Oct 2020 19:01:24

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:01:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '801d2d47-da98-45ba-bb41-2f2c89b2d1ee'	System	04 Oct 2020 19:01:24
User entered '04 Oct 2020 15:01'	System	04 Oct 2020 19:01:24

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:02:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '854e1590-1669-4408-ae34-1454194e59ee'	System	28 Sep 2020 16:04:29
User entered 'None (0)'	System	28 Sep 2020 16:04:29

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:02:50', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '854e1590-1669-4408-ae34-1454194e59ee'	System	28 Sep 2020 16:04:29
User entered 'None (0)'	System	28 Sep 2020 16:04:29

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:02:58', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '854e1590-1669-4408-ae34-1454194e59ee'	System	28 Sep 2020 16:04:29
User entered 'None (0)'	System	28 Sep 2020 16:04:29

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:03:08', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '854e1590-1669-4408-ae34-1454194e59ee'	System	28 Sep 2020 16:04:29
User entered 'None (0)'	System	28 Sep 2020 16:04:29

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:03:13', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '854e1590-1669-4408-ae34-1454194e59ee'	System	28 Sep 2020 16:04:29
User entered 'None (0)'	System	28 Sep 2020 16:04:29

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:03:23', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '854e1590-1669-4408-ae34-1454194e59ee'	System	28 Sep 2020 16:04:29
User entered 'None (0)'	System	28 Sep 2020 16:04:29

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:03:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '854e1590-1669-4408-ae34-1454194e59ee'	System	28 Sep 2020 16:04:29
User entered 'No (N)'	System	28 Sep 2020 16:04:29

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-28T12:03:43', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '854e1590-1669-4408-ae34-1454194e59ee'	System	28 Sep 2020 16:04:29
User entered '28 Sep 2020 12:03'	System	28 Sep 2020 16:04:29

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 11:51'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 14:21'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:26:18', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c4f27a7d-1455-4c4e-b624-98f6b07b6d2d'	System	29 Sep 2020 13:27:47
User entered 'None (0)'	System	29 Sep 2020 13:27:47

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:26:31', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c4f27a7d-1455-4c4e-b624-98f6b07b6d2d'	System	29 Sep 2020 13:27:47
User entered 'None (0)'	System	29 Sep 2020 13:27:47

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:26:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c4f27a7d-1455-4c4e-b624-98f6b07b6d2d'	System	29 Sep 2020 13:27:47
User entered 'None (0)'	System	29 Sep 2020 13:27:47

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:26:50', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c4f27a7d-1455-4c4e-b624-98f6b07b6d2d'	System	29 Sep 2020 13:27:47
User entered 'None (0)'	System	29 Sep 2020 13:27:47

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:26:59', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c4f27a7d-1455-4c4e-b624-98f6b07b6d2d'	System	29 Sep 2020 13:27:47
User entered 'None (0)'	System	29 Sep 2020 13:27:47

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:27:12', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c4f27a7d-1455-4c4e-b624-98f6b07b6d2d'	System	29 Sep 2020 13:27:47
User entered 'None (0)'	System	29 Sep 2020 13:27:47

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:27:21', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c4f27a7d-1455-4c4e-b624-98f6b07b6d2d'	System	29 Sep 2020 13:27:47
User entered 'No (N)'	System	29 Sep 2020 13:27:47

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-29T09:27:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'c4f27a7d-1455-4c4e-b624-98f6b07b6d2d'	System	29 Sep 2020 13:27:47
User entered '29 Sep 2020 09:27'	System	29 Sep 2020 13:27:47

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Sep 2020 15:16'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 2'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:31:02', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '591cd0a9-e48d-4d58-a564-bdd22d2ad496'	System	30 Sep 2020 14:32:02
User entered 'None (0)'	System	30 Sep 2020 14:32:02

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:31:15', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '591cd0a9-e48d-4d58-a564-bdd22d2ad496'	System	30 Sep 2020 14:32:02
User entered 'None (0)'	System	30 Sep 2020 14:32:02

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:31:25', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '591cd0a9-e48d-4d58-a564-bdd22d2ad496'	System	30 Sep 2020 14:32:02
User entered 'None (0)'	System	30 Sep 2020 14:32:02

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:31:30', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '591cd0a9-e48d-4d58-a564-bdd22d2ad496'	System	30 Sep 2020 14:32:02
User entered 'None (0)'	System	30 Sep 2020 14:32:02

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:31:35', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '591cd0a9-e48d-4d58-a564-bdd22d2ad496'	System	30 Sep 2020 14:32:02
User entered 'None (0)'	System	30 Sep 2020 14:32:02

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:31:38', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '591cd0a9-e48d-4d58-a564-bdd22d2ad496'	System	30 Sep 2020 14:32:02
User entered 'None (0)'	System	30 Sep 2020 14:32:02

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:31:47', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '591cd0a9-e48d-4d58-a564-bdd22d2ad496'	System	30 Sep 2020 14:32:02
User entered 'No (N)'	System	30 Sep 2020 14:32:02

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T10:31:57', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '591cd0a9-e48d-4d58-a564-bdd22d2ad496'	System	30 Sep 2020 14:32:02
User entered '30 Sep 2020 10:31'	System	30 Sep 2020 14:32:02

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 3'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:29:54', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd3ffc69a-1f00-45d3-a3cd-cd8fe5a4244b'	System	30 Sep 2020 23:30:48
User entered 'None (0)'	System	30 Sep 2020 23:30:48

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:29:58', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd3ffc69a-1f00-45d3-a3cd-cd8fe5a4244b'	System	30 Sep 2020 23:30:48
User entered 'None (0)'	System	30 Sep 2020 23:30:48

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:30:03', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd3ffc69a-1f00-45d3-a3cd-cd8fe5a4244b'	System	30 Sep 2020 23:30:48
User entered 'None (0)'	System	30 Sep 2020 23:30:48

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:30:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd3ffc69a-1f00-45d3-a3cd-cd8fe5a4244b'	System	30 Sep 2020 23:30:48
User entered 'None (0)'	System	30 Sep 2020 23:30:48

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:30:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd3ffc69a-1f00-45d3-a3cd-cd8fe5a4244b'	System	30 Sep 2020 23:30:48
User entered 'None (0)'	System	30 Sep 2020 23:30:48

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:30:17', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd3ffc69a-1f00-45d3-a3cd-cd8fe5a4244b'	System	30 Sep 2020 23:30:48
User entered 'None (0)'	System	30 Sep 2020 23:30:48

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:30:22', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd3ffc69a-1f00-45d3-a3cd-cd8fe5a4244b'	System	30 Sep 2020 23:30:48
User entered 'No (N)'	System	30 Sep 2020 23:30:48

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-09-30T19:30:45', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd3ffc69a-1f00-45d3-a3cd-cd8fe5a4244b'	System	30 Sep 2020 23:30:48
User entered '30 Sep 2020 19:30'	System	30 Sep 2020 23:30:48

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 4'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:26:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8a516a16-1fd8-40b0-8e8c-19b4fb4a8f8f'	System	01 Oct 2020 16:27:24
User entered 'None (0)'	System	01 Oct 2020 16:27:24

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:26:32', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8a516a16-1fd8-40b0-8e8c-19b4fb4a8f8f'	System	01 Oct 2020 16:27:24
User entered 'None (0)'	System	01 Oct 2020 16:27:24

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:26:39', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8a516a16-1fd8-40b0-8e8c-19b4fb4a8f8f'	System	01 Oct 2020 16:27:24
User entered 'None (0)'	System	01 Oct 2020 16:27:24

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:26:46', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8a516a16-1fd8-40b0-8e8c-19b4fb4a8f8f' User entered 'None (0)'	System	01 Oct 2020 16:27:24
	System	01 Oct 2020 16:27:24

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:26:52', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8a516a16-1fd8-40b0-8e8c-19b4fb4a8f8f'	System	01 Oct 2020 16:27:24
User entered 'None (0)'	System	01 Oct 2020 16:27:24

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:26:59', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8a516a16-1fd8-40b0-8e8c-19b4fb4a8f8f'	System	01 Oct 2020 16:27:24
User entered 'None (0)'	System	01 Oct 2020 16:27:24

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:27:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8a516a16-1fd8-40b0-8e8c-19b4fb4a8f8f'	System	01 Oct 2020 16:27:24
User entered 'No (N)'	System	01 Oct 2020 16:27:24

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-01T12:27:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8a516a16-1fd8-40b0-8e8c-19b4fb4a8f8f'	System	01 Oct 2020 16:27:24
User entered '01 Oct 2020 12:27'	System	01 Oct 2020 16:27:24

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 5'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:37', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a8cfbfb3-cbc7-446b-933d-a25433088b3e'	System	02 Oct 2020 17:40:36
User entered 'None (0)'	System	02 Oct 2020 17:40:36

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:43', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a8cfbfb3-cbc7-446b-933d-a25433088b3e'	System	02 Oct 2020 17:40:36
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:40:36

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:47', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a8cfbfb3-cbc7-446b-933d-a25433088b3e'	System	02 Oct 2020 17:40:36
User entered 'None (0)'	System	02 Oct 2020 17:40:36

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:51', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a8cfbfb3-cbc7-446b-933d-a25433088b3e'	System	02 Oct 2020 17:40:36
User entered 'None (0)'	System	02 Oct 2020 17:40:36

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:54', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a8cfbfb3-cbc7-446b-933d-a25433088b3e'	System	02 Oct 2020 17:40:36
User entered 'None (0)'	System	02 Oct 2020 17:40:36

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:39:58', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a8cfbfb3-cbc7-446b-933d-a25433088b3e'	System	02 Oct 2020 17:40:36
User entered 'None (0)'	System	02 Oct 2020 17:40:36

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:40:21', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a8cfbf3-cbc7-446b-933d-a25433088b3e'	System	02 Oct 2020 17:40:36
User entered 'No (N)'	System	02 Oct 2020 17:40:36

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-02T13:40:31', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a8cfbfb3-cbc7-446b-933d-a25433088b3e'	System	02 Oct 2020 17:40:36
User entered '02 Oct 2020 13:40'	System	02 Oct 2020 17:40:36

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 6'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:35', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ffebb49c-565c-48aa-ad55-f3c8ee11fb2a'	System	03 Oct 2020 17:58:31
User entered 'None (0)'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:45', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ffebb49c-565c-48aa-ad55-f3c8ee11fb2a'	System	03 Oct 2020 17:58:31
User entered 'No interference with activity (1)'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:49', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ffebb49c-565c-48aa-ad55-f3c8ee11fb2a'	System	03 Oct 2020 17:58:31
User entered 'None (0)'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:54', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ffebb49c-565c-48aa-ad55-f3c8ee11fb2a'	System	03 Oct 2020 17:58:31
User entered 'None (0)'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:57:58', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ffebb49c-565c-48aa-ad55-f3c8ee11fb2a'	System	03 Oct 2020 17:58:31
User entered 'None (0)'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:58:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ffebb49c-565c-48aa-ad55-f3c8ee11fb2a'	System	03 Oct 2020 17:58:31
User entered 'None (0)'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:58:18', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ffebb49c-565c-48aa-ad55-f3c8ee11fb2a'	System	03 Oct 2020 17:58:31
User entered 'No (N)'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-03T13:58:27', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ffebb49c-565c-48aa-ad55-f3c8ee11fb2a'	System	03 Oct 2020 17:58:31
User entered '03 Oct 2020 13:58'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	28 Sep 2020 15:45:13
User entered 'Day 7'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:01:18', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f27f0d2f-76ee-46c5-bc45-d6342a10d15b'	System	04 Oct 2020 19:02:12
User entered 'None (0)'	System	04 Oct 2020 19:02:12

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:01:25', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f27f0d2f-76ee-46c5-bc45-d6342a10d15b'	System	04 Oct 2020 19:02:12
User entered 'No interference with activity (1)'	System	04 Oct 2020 19:02:12

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:01:30', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f27f0d2f-76ee-46c5-bc45-d6342a10d15b'	System	04 Oct 2020 19:02:12
User entered 'None (0)'	System	04 Oct 2020 19:02:12

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:01:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f27f0d2f-76ee-46c5-bc45-d6342a10d15b'	System	04 Oct 2020 19:02:12
User entered 'None (0)'	System	04 Oct 2020 19:02:12

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:01:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f27f0d2f-76ee-46c5-bc45-d6342a10d15b'	System	04 Oct 2020 19:02:12
User entered 'None (0)'	System	04 Oct 2020 19:02:12

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:01:46', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f27f0d2f-76ee-46c5-bc45-d6342a10d15b'	System	04 Oct 2020 19:02:12
User entered 'None (0)'	System	04 Oct 2020 19:02:12

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:01:54', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f27f0d2f-76ee-46c5-bc45-d6342a10d15b'	System	04 Oct 2020 19:02:12
User entered 'No (N)'	System	04 Oct 2020 19:02:12

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-04T15:02:09', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f27f0d2f-76ee-46c5-bc45-d6342a10d15b'	System	04 Oct 2020 19:02:12
User entered '04 Oct 2020 15:02'	System	04 Oct 2020 19:02:12

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:45:13

US3822443

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	03 Oct 2020 17:58:31
User entered 'Day 8'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-05T18:45:53', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '438563b7-03b0-4b67-b772-1725038e9954'	System	05 Oct 2020 22:46:08
User entered 'None (0)'	System	05 Oct 2020 22:46:08

US3822443

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-05T18:46:04', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '438563b7-03b0-4b67-b772-1725038e9954'	System	05 Oct 2020 22:46:08
User entered '05 Oct 2020 18:46'	System	05 Oct 2020 22:46:08

US3822443

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	03 Oct 2020 17:58:31
User entered 'Day 8'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-05T18:46:18', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '16b7c56f-c398-4380-8bcb-c0e6615ad12c'	System	05 Oct 2020 22:46:38
User entered 'No (N)'	System	05 Oct 2020 22:46:38

US3822443

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-05T18:46:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '16b7c56f-c398-4380-8bcb-c0e6615ad12c'	System	05 Oct 2020 22:46:38
User entered '05 Oct 2020 18:46'	System	05 Oct 2020 22:46:38

US3822443

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 17:58:31

US3822443

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 17:58:31

US3822443

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	27 Oct 2020 21:11:36

US3822443

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '6 Oct 2020'	Krishna Shah (b) (4)	27 Oct 2020 21:11:36

US3822443

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	27 Oct 2020 21:11:36

US3822443

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) Krishna Shah (b) (4)	27 Oct 2020 21:11:36
	(b) (4)	

US3822443

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:52:12

US3822443

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	27 Oct 2020 13:52:12

US3822443

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	27 Oct 2020 21:12:13

US3822443

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '13 Oct 2020'	Krishna Shah (b) (4)	27 Oct 2020 21:12:13

US3822443

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:12:13

US3822443

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:12:13

US3822443

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:52:18

US3822443

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	27 Oct 2020 13:52:18

US3822443

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	27 Oct 2020 21:12:46

US3822443

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '20 Oct 2020'	Krishna Shah (b) (4)	27 Oct 2020 21:12:46

US3822443

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	27 Oct 2020 21:12:46

US3822443

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) Krishna Shah (b) (4)	27 Oct 2020 21:12:46
	(b) (4)	

US3822443

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:52:29

US3822443

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	27 Oct 2020 13:52:29

US3822443

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:52:46

US3822443

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:52:46

US3822443

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:52:46

US3822443

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'VISIT2'	System	27 Oct 2020 13:52:46

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User accepted default value 'Pre-Dose (PREDOSE)'	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '27 Oct 2020'	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '08:55'	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '27 Oct 2020 08:55'	System	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '98.3' F	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '87'	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'bpm'	System	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '20'	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'breaths/min'	System	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '112'	Krishna Shah (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 10:42:58
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI this is NCS' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 18:13:58
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		27 Oct 2020 21:14:56
User entered '55'	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	27 Oct 2020 21:14:56

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User accepted default value 'Post-Dose (POSTDOSE)'	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '27 Oct 2020'	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '10:10'	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '27 Oct 2020 10:10'	System	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '98.6' F	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '87'	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'bpm'	System	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '20'	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'breaths/min'	System	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '123'	Krishna Shah (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 10:43:11
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI this is NCS' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 18:14:08
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		27 Oct 2020 21:16:04
User entered '55'	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	27 Oct 2020 21:16:04

US3822443

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	27 Oct 2020 21:16:18

US3822443

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	27 Oct 2020 21:16:18

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'MRNA-1273 OR PLACEBO'	System	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '09:40'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '27 Oct 2020 09:40'	System	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'ONCE'	System	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'INTRAMUSCULAR'	System	27 Oct 2020 13:53:30

US3822443

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	27 Oct 2020 21:16:41

US3822443

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '27 Oct 2020'	Krishna Shah (b) (4)	27 Oct 2020 21:16:41

US3822443

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '09:04'	Krishna Shah (b) (4)	27 Oct 2020 21:16:41

US3822443

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '27 Oct 2020 09:04'	System	27 Oct 2020 21:16:41

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:57:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '27 Oct 2020'	Krishna Shah (b) (4)	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '09:10'	Krishna Shah (b) (4)	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '27 Oct 2020 09:10'	System	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	27 Oct 2020 21:17:05

US3822443

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:53:41

US3822443

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	27 Oct 2020 13:53:41

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:07:56', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '09075eb9-3806-4030-9fed-b02e0a943889'	System	27 Oct 2020 14:09:07
User entered 'Yes (Y)'	System	27 Oct 2020 14:09:07

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:08:37', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '09075eb9-3806-4030-9fed-b02e0a943889' User entered '98.6'	System	27 Oct 2020 14:09:07
	System	27 Oct 2020 14:09:07

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:08:48', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '09075eb9-3806-4030-9fed-b02e0a943889'	System	27 Oct 2020 14:09:07
User entered 'No (N)'	System	27 Oct 2020 14:09:07

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:09:02', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '09075eb9-3806-4030-9fed-b02e0a943889' User entered '27 Oct 2020 10:09'	System	27 Oct 2020 14:09:07
	System	27 Oct 2020 14:09:07

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 10:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 12:30'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:40:28', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f3e60fc5-f037-4438-937c-03e58e35016e'	System	27 Oct 2020 21:41:04
User entered 'Yes (Y)'	System	27 Oct 2020 21:41:04

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:40:48', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f3e60fc5-f037-4438-937c-03e58e35016e' User entered '98.5'	System	27 Oct 2020 21:41:04
	System	27 Oct 2020 21:41:04

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:40:53', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f3e60fc5-f037-4438-937c-03e58e35016e'	System	27 Oct 2020 21:41:04
User entered 'No (N)'	System	27 Oct 2020 21:41:04

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:41:01', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f3e60fc5-f037-4438-937c-03e58e35016e' User entered '27 Oct 2020 17:41'	System	27 Oct 2020 21:41:04
	System	27 Oct 2020 21:41:04

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 13:25'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 2'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:39:05', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7c326db7-783f-4bc5-a6f5-8e39e53f8dd0'	System	28 Oct 2020 16:39:54
User entered 'Yes (Y)'	System	28 Oct 2020 16:39:54

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:39:29', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7c326db7-783f-4bc5-a6f5-8e39e53f8dd0'	System	28 Oct 2020 16:39:54
User entered '98.0'	System	28 Oct 2020 16:39:54

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:39:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7c326db7-783f-4bc5-a6f5-8e39e53f8dd0'	System	28 Oct 2020 16:39:54
User entered 'No (N)'	System	28 Oct 2020 16:39:54

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:39:51', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7c326db7-783f-4bc5-a6f5-8e39e53f8dd0'	System	28 Oct 2020 16:39:54
User entered '28 Oct 2020 12:39'	System	28 Oct 2020 16:39:54

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 3'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:14:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f083ca79-185f-477a-9840-7ac5932f7fa9'	System	29 Oct 2020 18:15:26
User entered 'Yes (Y)'	System	29 Oct 2020 18:15:26

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:14:58', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f083ca79-185f-477a-9840-7ac5932f7fa9'	System	29 Oct 2020 18:15:26
User entered '96.0'	System	29 Oct 2020 18:15:26

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:15:04', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f083ca79-185f-477a-9840-7ac5932f7fa9'	System	29 Oct 2020 18:15:26
User entered 'No (N)'	System	29 Oct 2020 18:15:26

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:15:23', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f083ca79-185f-477a-9840-7ac5932f7fa9'	System	29 Oct 2020 18:15:26
User entered '29 Oct 2020 14:15'	System	29 Oct 2020 18:15:26

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 4'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:55:06', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '5210da41-bd00-4041-b4ba-21c58e29c1ee'	System	30 Oct 2020 16:55:39
User entered 'Yes (Y)'	System	30 Oct 2020 16:55:39

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:55:30', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '5210da41-bd00-4041-b4ba-21c58e29c1ee' User entered '96.9'	System	30 Oct 2020 16:55:39
	System	30 Oct 2020 16:55:39

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:55:23', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '5210da41-bd00-4041-b4ba-21c58e29c1ee'	System	30 Oct 2020 16:55:39
User entered 'No (N)'	System	30 Oct 2020 16:55:39

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:55:36', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '5210da41-bd00-4041-b4ba-21c58e29c1ee'	System	30 Oct 2020 16:55:39
User entered '30 Oct 2020 12:55'	System	30 Oct 2020 16:55:39

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 5'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:13:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '78aaec66-5387-41e1-ab00-5ef5cb2c002c'	System	31 Oct 2020 18:14:43
User entered 'Yes (Y)'	System	31 Oct 2020 18:14:43

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:14:25', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '78aaec66-5387-41e1-ab00-5ef5cb2c002c' User entered '98.2'	System	31 Oct 2020 18:14:43
	System	31 Oct 2020 18:14:43

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:14:32', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '78aaec66-5387-41e1-ab00-5ef5cb2c002c'	System	31 Oct 2020 18:14:43
User entered 'No (N)'	System	31 Oct 2020 18:14:43

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:14:40', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '78aaec66-5387-41e1-ab00-5ef5cb2c002c'	System	31 Oct 2020 18:14:43
User entered '31 Oct 2020 14:14'	System	31 Oct 2020 18:14:43

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 6'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:11:56', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ff77a071-3eb9-40e0-afc9-f9abd95cb9b0'	System	01 Nov 2020 20:12:25
User entered 'Yes (Y)'	System	01 Nov 2020 20:12:25

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:12:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ff77a071-3eb9-40e0-afc9-f9abd95cb9b0'	System	01 Nov 2020 20:12:25
User entered '98.5'	System	01 Nov 2020 20:12:25

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:12:15', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ff77a071-3eb9-40e0-afc9-f9abd95cb9b0'	System	01 Nov 2020 20:12:25
User entered 'No (N)'	System	01 Nov 2020 20:12:25

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:12:21', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ff77a071-3eb9-40e0-afc9-f9abd95cb9b0'	System	01 Nov 2020 20:12:25
User entered '01 Nov 2020 15:12'	System	01 Nov 2020 20:12:25

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 7'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:32:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'afd25e85-b3b8-4434-9867-9cc19db2cd3c'	System	02 Nov 2020 23:32:37
User entered 'Yes (Y)'	System	02 Nov 2020 23:32:37

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:32:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'afd25e85-b3b8-4434-9867-9cc19db2cd3c'	System	02 Nov 2020 23:32:37
User entered '98.0'	System	02 Nov 2020 23:32:37

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:32:25', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'afd25e85-b3b8-4434-9867-9cc19db2cd3c'	System	02 Nov 2020 23:32:37
User entered 'No (N)'	System	02 Nov 2020 23:32:37

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:32:33', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'afd25e85-b3b8-4434-9867-9cc19db2cd3c'	System	02 Nov 2020 23:32:37
User entered '02 Nov 2020 18:32'	System	02 Nov 2020 23:32:37

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:09:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f1bc0283-60d7-4f9b-9185-c19b63b841ca'	System	27 Oct 2020 14:09:52
User entered 'None (1)'	System	27 Oct 2020 14:09:52

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:09:26', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f1bc0283-60d7-4f9b-9185-c19b63b841ca'	System	27 Oct 2020 14:09:52
User entered 'No (N)'	System	27 Oct 2020 14:09:52

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:09:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f1bc0283-60d7-4f9b-9185-c19b63b841ca'	System	27 Oct 2020 14:09:52
User entered 'No (N)'	System	27 Oct 2020 14:09:52

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:09:39', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f1bc0283-60d7-4f9b-9185-c19b63b841ca'	System	27 Oct 2020 14:09:52
User entered 'None (1)'	System	27 Oct 2020 14:09:52

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:09:48', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f1bc0283-60d7-4f9b-9185-c19b63b841ca'	System	27 Oct 2020 14:09:52
User entered '27 Oct 2020 10:09'	System	27 Oct 2020 14:09:52

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 10:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 12:30'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:41:14', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69aa8f60-28be-4109-9f33-173967f11804'	System	27 Oct 2020 21:41:43
User entered 'None (1)'	System	27 Oct 2020 21:41:43

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:41:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69aa8f60-28be-4109-9f33-173967f11804'	System	27 Oct 2020 21:41:43
User entered 'No (N)'	System	27 Oct 2020 21:41:43

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:41:24', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69aa8f60-28be-4109-9f33-173967f11804'	System	27 Oct 2020 21:41:43
User entered 'No (N)'	System	27 Oct 2020 21:41:43

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:41:31', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69aa8f60-28be-4109-9f33-173967f11804'	System	27 Oct 2020 21:41:43
User entered 'None (1)'	System	27 Oct 2020 21:41:43

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:41:40', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '69aa8f60-28be-4109-9f33-173967f11804'	System	27 Oct 2020 21:41:43
User entered '27 Oct 2020 17:41'	System	27 Oct 2020 21:41:43

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 13:25'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 2'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:40:09', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60185f32-f307-4a1f-8c00-2df15c09f67a'	System	28 Oct 2020 16:40:46
User entered 'Does not interfere with activity (2)'	System	28 Oct 2020 16:40:46

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:40:14', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60185f32-f307-4a1f-8c00-2df15c09f67a'	System	28 Oct 2020 16:40:46
User entered 'No (N)'	System	28 Oct 2020 16:40:46

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:40:21', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60185f32-f307-4a1f-8c00-2df15c09f67a'	System	28 Oct 2020 16:40:46
User entered 'No (N)'	System	28 Oct 2020 16:40:46

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:40:32', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60185f32-f307-4a1f-8c00-2df15c09f67a'	System	28 Oct 2020 16:40:46
User entered 'None (1)'	System	28 Oct 2020 16:40:46

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:40:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '60185f32-f307-4a1f-8c00-2df15c09f67a'	System	28 Oct 2020 16:40:46
User entered '28 Oct 2020 12:40'	System	28 Oct 2020 16:40:46

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 3'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:15:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fb3acc54-afb0-48d2-b533-f5ee81c7a17f'	System	29 Oct 2020 18:16:38
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 18:16:38

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:15:46', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fb3acc54-afb0-48d2-b533-f5ee81c7a17f'	System	29 Oct 2020 18:16:38
User entered 'No (N)'	System	29 Oct 2020 18:16:38

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:16:05', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fb3acc54-afb0-48d2-b533-f5ee81c7a17f'	System	29 Oct 2020 18:16:38
User entered 'No (N)'	System	29 Oct 2020 18:16:38

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:16:17', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fb3acc54-afb0-48d2-b533-f5ee81c7a17f'	System	29 Oct 2020 18:16:38
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 18:16:38

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:16:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fb3acc54-afb0-48d2-b533-f5ee81c7a17f'	System	29 Oct 2020 18:16:38
User entered '29 Oct 2020 14:16'	System	29 Oct 2020 18:16:38

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 4'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:55:49', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1eca5f2d-d9fd-472b-b915-96985e738b3a'	System	30 Oct 2020 16:56:36
User entered 'Does not interfere with activity (2)'	System	30 Oct 2020 16:56:36

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:56:29', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1eca5f2d-d9fd-472b-b915-96985e738b3a'	System	30 Oct 2020 16:56:36
User entered 'No (N)'	System	30 Oct 2020 16:56:36

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:55:59', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1eca5f2d-d9fd-472b-b915-96985e738b3a'	System	30 Oct 2020 16:56:36
User entered 'No (N)'	System	30 Oct 2020 16:56:36

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:56:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1eca5f2d-d9fd-472b-b915-96985e738b3a'	System	30 Oct 2020 16:56:36
User entered 'None (1)'	System	30 Oct 2020 16:56:36

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:56:32', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1eca5f2d-d9fd-472b-b915-96985e738b3a'	System	30 Oct 2020 16:56:36
User entered '30 Oct 2020 12:56'	System	30 Oct 2020 16:56:36

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 5'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:14:48', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fae17f7d-6038-4f32-a907-96696059de05'	System	31 Oct 2020 18:15:14
User entered 'None (1)'	System	31 Oct 2020 18:15:14

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:14:53', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fae17f7d-6038-4f32-a907-96696059de05'	System	31 Oct 2020 18:15:14
User entered 'No (N)'	System	31 Oct 2020 18:15:14

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:14:59', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fae17f7d-6038-4f32-a907-96696059de05'	System	31 Oct 2020 18:15:14
User entered 'No (N)'	System	31 Oct 2020 18:15:14

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:03', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fae17f7d-6038-4f32-a907-96696059de05'	System	31 Oct 2020 18:15:14
User entered 'None (1)'	System	31 Oct 2020 18:15:14

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:13', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'fae17f7d-6038-4f32-a907-96696059de05'	System	31 Oct 2020 18:15:14
User entered '31 Oct 2020 14:15'	System	31 Oct 2020 18:15:14

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 6'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:12:30', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '6e2d6278-75f5-4afd-a847-0184998de7a3'	System	01 Nov 2020 20:13:06
User entered 'None (1)'	System	01 Nov 2020 20:13:06

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:12:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '6e2d6278-75f5-4afd-a847-0184998de7a3'	System	01 Nov 2020 20:13:06
User entered 'No (N)'	System	01 Nov 2020 20:13:06

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:12:38', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '6e2d6278-75f5-4afd-a847-0184998de7a3'	System	01 Nov 2020 20:13:06
User entered 'No (N)'	System	01 Nov 2020 20:13:06

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:12:47', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '6e2d6278-75f5-4afd-a847-0184998de7a3'	System	01 Nov 2020 20:13:06
User entered 'None (1)'	System	01 Nov 2020 20:13:06

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:04', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '6e2d6278-75f5-4afd-a847-0184998de7a3'	System	01 Nov 2020 20:13:06
User entered '01 Nov 2020 15:13'	System	01 Nov 2020 20:13:06

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 7'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:32:41', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '72a07ffc-09e3-40b0-a767-cb975417d551'	System	02 Nov 2020 23:33:19
User entered 'None (1)'	System	02 Nov 2020 23:33:19

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:32:46', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '72a07ffc-09e3-40b0-a767-cb975417d551'	System	02 Nov 2020 23:33:19
User entered 'No (N)'	System	02 Nov 2020 23:33:19

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:32:51', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '72a07ffc-09e3-40b0-a767-cb975417d551'	System	02 Nov 2020 23:33:19
User entered 'No (N)'	System	02 Nov 2020 23:33:19

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:32:56', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '72a07ffc-09e3-40b0-a767-cb975417d551'	System	02 Nov 2020 23:33:19
User entered 'None (1)'	System	02 Nov 2020 23:33:19

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:33:15', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '72a07ffc-09e3-40b0-a767-cb975417d551'	System	02 Nov 2020 23:33:19
User entered '02 Nov 2020 18:33'	System	02 Nov 2020 23:33:19

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:09:59', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8c1f952f-3cfe-46e5-90bb-1e23aacf6292'	System	27 Oct 2020 14:11:16
User entered 'None (0)'	System	27 Oct 2020 14:11:16

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:10:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8c1f952f-3cfe-46e5-90bb-1e23aacf6292'	System	27 Oct 2020 14:11:16
User entered 'None (0)'	System	27 Oct 2020 14:11:16

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:10:13', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8c1f952f-3cfe-46e5-90bb-1e23aacf6292'	System	27 Oct 2020 14:11:16
User entered 'None (0)'	System	27 Oct 2020 14:11:16

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:10:18', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8c1f952f-3cfe-46e5-90bb-1e23aacf6292'	System	27 Oct 2020 14:11:16
User entered 'None (0)'	System	27 Oct 2020 14:11:16

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:10:23', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8c1f952f-3cfe-46e5-90bb-1e23aacf6292'	System	27 Oct 2020 14:11:16
User entered 'None (0)'	System	27 Oct 2020 14:11:16

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:10:30', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8c1f952f-3cfe-46e5-90bb-1e23aacf6292'	System	27 Oct 2020 14:11:16
User entered 'None (0)'	System	27 Oct 2020 14:11:16

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:10:39', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8c1f952f-3cfe-46e5-90bb-1e23aacf6292'	System	27 Oct 2020 14:11:16
User entered 'No (N)'	System	27 Oct 2020 14:11:16

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T10:11:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8c1f952f-3cfe-46e5-90bb-1e23aacf6292'	System	27 Oct 2020 14:11:16
User entered '27 Oct 2020 10:11'	System	27 Oct 2020 14:11:16

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 10:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 12:30'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:41:49', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd819bd30-cbc3-4dd6-beb1-69b82cc86fb9'	System	27 Oct 2020 21:42:42
User entered 'None (0)'	System	27 Oct 2020 21:42:42

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:41:56', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd819bd30-cbc3-4dd6-beb1-69b82cc86fb9'	System	27 Oct 2020 21:42:42
User entered 'None (0)'	System	27 Oct 2020 21:42:42

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:42:02', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd819bd30-cbc3-4dd6-beb1-69b82cc86fb9'	System	27 Oct 2020 21:42:42
User entered 'None (0)'	System	27 Oct 2020 21:42:42

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:42:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd819bd30-cbc3-4dd6-beb1-69b82cc86fb9'	System	27 Oct 2020 21:42:42
User entered 'None (0)'	System	27 Oct 2020 21:42:42

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:42:12', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd819bd30-cbc3-4dd6-beb1-69b82cc86fb9'	System	27 Oct 2020 21:42:42
User entered 'None (0)'	System	27 Oct 2020 21:42:42

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:42:17', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd819bd30-cbc3-4dd6-beb1-69b82cc86fb9'	System	27 Oct 2020 21:42:42
User entered 'None (0)'	System	27 Oct 2020 21:42:42

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:42:23', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd819bd30-cbc3-4dd6-beb1-69b82cc86fb9'	System	27 Oct 2020 21:42:42
User entered 'No (N)'	System	27 Oct 2020 21:42:42

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-27T17:42:40', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd819bd30-cbc3-4dd6-beb1-69b82cc86fb9'	System	27 Oct 2020 21:42:42
User entered '27 Oct 2020 17:42'	System	27 Oct 2020 21:42:42

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '27 Oct 2020 13:25'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 2'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:40:50', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ae10537a-093e-4ecd-bdab-244acd71e350'	System	28 Oct 2020 16:41:38
User entered 'None (0)'	System	28 Oct 2020 16:41:38

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:40:59', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ae10537a-093e-4ecd-bdab-244acd71e350'	System	28 Oct 2020 16:41:38
User entered 'None (0)'	System	28 Oct 2020 16:41:38

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:41:04', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ae10537a-093e-4ecd-bdab-244acd71e350'	System	28 Oct 2020 16:41:38
User entered 'None (0)'	System	28 Oct 2020 16:41:38

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:41:09', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ae10537a-093e-4ecd-bdab-244acd71e350'	System	28 Oct 2020 16:41:38
User entered 'None (0)'	System	28 Oct 2020 16:41:38

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:41:15', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ae10537a-093e-4ecd-bdab-244acd71e350'	System	28 Oct 2020 16:41:38
User entered 'None (0)'	System	28 Oct 2020 16:41:38

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:41:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ae10537a-093e-4ecd-bdab-244acd71e350'	System	28 Oct 2020 16:41:38
User entered 'None (0)'	System	28 Oct 2020 16:41:38

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:41:25', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ae10537a-093e-4ecd-bdab-244acd71e350'	System	28 Oct 2020 16:41:38
User entered 'No (N)'	System	28 Oct 2020 16:41:38

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-28T12:41:33', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'ae10537a-093e-4ecd-bdab-244acd71e350'	System	28 Oct 2020 16:41:38
User entered '28 Oct 2020 12:41'	System	28 Oct 2020 16:41:38

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 3'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:16:42', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7d6a7588-ad57-4f76-8dbc-aa1631ac3d4c'	System	29 Oct 2020 18:17:36
User entered 'None (0)'	System	29 Oct 2020 18:17:36

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:16:47', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7d6a7588-ad57-4f76-8dbc-aa1631ac3d4c'	System	29 Oct 2020 18:17:36
User entered 'None (0)'	System	29 Oct 2020 18:17:36

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:16:52', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7d6a7588-ad57-4f76-8dbc-aa1631ac3d4c'	System	29 Oct 2020 18:17:36
User entered 'None (0)'	System	29 Oct 2020 18:17:36

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:16:56', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7d6a7588-ad57-4f76-8dbc-aa1631ac3d4c'	System	29 Oct 2020 18:17:36
User entered 'None (0)'	System	29 Oct 2020 18:17:36

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:17:26', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7d6a7588-ad57-4f76-8dbc-aa1631ac3d4c'	System	29 Oct 2020 18:17:36
User entered 'None (0)'	System	29 Oct 2020 18:17:36

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:17:05', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7d6a7588-ad57-4f76-8dbc-aa1631ac3d4c'	System	29 Oct 2020 18:17:36
User entered 'None (0)'	System	29 Oct 2020 18:17:36

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:17:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7d6a7588-ad57-4f76-8dbc-aa1631ac3d4c'	System	29 Oct 2020 18:17:36
User entered 'No (N)'	System	29 Oct 2020 18:17:36

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-29T14:17:32', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7d6a7588-ad57-4f76-8dbc-aa1631ac3d4c'	System	29 Oct 2020 18:17:36
User entered '29 Oct 2020 14:17'	System	29 Oct 2020 18:17:36

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 4'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:56:40', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1781306a-7a74-4cba-be9e-bb3c4244b180'	System	30 Oct 2020 16:57:43
User entered 'None (0)'	System	30 Oct 2020 16:57:43

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:56:46', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1781306a-7a74-4cba-be9e-bb3c4244b180'	System	30 Oct 2020 16:57:43
User entered 'None (0)'	System	30 Oct 2020 16:57:43

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:56:50', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1781306a-7a74-4cba-be9e-bb3c4244b180'	System	30 Oct 2020 16:57:43
User entered 'None (0)'	System	30 Oct 2020 16:57:43

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:56:55', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1781306a-7a74-4cba-be9e-bb3c4244b180'	System	30 Oct 2020 16:57:43
User entered 'None (0)'	System	30 Oct 2020 16:57:43

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:57:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1781306a-7a74-4cba-be9e-bb3c4244b180'	System	30 Oct 2020 16:57:43
User entered 'None (0)'	System	30 Oct 2020 16:57:43

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:57:17', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1781306a-7a74-4cba-be9e-bb3c4244b180'	System	30 Oct 2020 16:57:43
User entered 'None (0)'	System	30 Oct 2020 16:57:43

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:57:22', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1781306a-7a74-4cba-be9e-bb3c4244b180'	System	30 Oct 2020 16:57:43
User entered 'No (N)'	System	30 Oct 2020 16:57:43

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-30T12:57:41', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '1781306a-7a74-4cba-be9e-bb3c4244b180'	System	30 Oct 2020 16:57:43
User entered '30 Oct 2020 12:57'	System	30 Oct 2020 16:57:43

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 5'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:20', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a0567195-d1e3-4e7b-8648-c165480d35b5'	System	31 Oct 2020 18:16:08
User entered 'None (0)'	System	31 Oct 2020 18:16:08

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:25', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a0567195-d1e3-4e7b-8648-c165480d35b5'	System	31 Oct 2020 18:16:08
User entered 'None (0)'	System	31 Oct 2020 18:16:08

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:29', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a0567195-d1e3-4e7b-8648-c165480d35b5'	System	31 Oct 2020 18:16:08
User entered 'None (0)'	System	31 Oct 2020 18:16:08

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:35', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a0567195-d1e3-4e7b-8648-c165480d35b5'	System	31 Oct 2020 18:16:08
User entered 'None (0)'	System	31 Oct 2020 18:16:08

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:40', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a0567195-d1e3-4e7b-8648-c165480d35b5'	System	31 Oct 2020 18:16:08
User entered 'None (0)'	System	31 Oct 2020 18:16:08

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:50', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a0567195-d1e3-4e7b-8648-c165480d35b5'	System	31 Oct 2020 18:16:08
User entered 'None (0)'	System	31 Oct 2020 18:16:08

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:15:54', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a0567195-d1e3-4e7b-8648-c165480d35b5'	System	31 Oct 2020 18:16:08
User entered 'No (N)'	System	31 Oct 2020 18:16:08

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-10-31T14:16:05', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'a0567195-d1e3-4e7b-8648-c165480d35b5'	System	31 Oct 2020 18:16:08
User entered '31 Oct 2020 14:16'	System	31 Oct 2020 18:16:08

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 6'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:10', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '2ca445f9-23a0-4304-99e7-1151341e00a6'	System	01 Nov 2020 20:13:59
User entered 'None (0)'	System	01 Nov 2020 20:13:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:14', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '2ca445f9-23a0-4304-99e7-1151341e00a6'	System	01 Nov 2020 20:13:59
User entered 'None (0)'	System	01 Nov 2020 20:13:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:18', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '2ca445f9-23a0-4304-99e7-1151341e00a6'	System	01 Nov 2020 20:13:59
User entered 'None (0)'	System	01 Nov 2020 20:13:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:24', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '2ca445f9-23a0-4304-99e7-1151341e00a6'	System	01 Nov 2020 20:13:59
User entered 'None (0)'	System	01 Nov 2020 20:13:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:31', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '2ca445f9-23a0-4304-99e7-1151341e00a6'	System	01 Nov 2020 20:13:59
User entered 'None (0)'	System	01 Nov 2020 20:13:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '2ca445f9-23a0-4304-99e7-1151341e00a6'	System	01 Nov 2020 20:13:59
User entered 'None (0)'	System	01 Nov 2020 20:13:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:41', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '2ca445f9-23a0-4304-99e7-1151341e00a6'	System	01 Nov 2020 20:13:59
User entered 'No (N)'	System	01 Nov 2020 20:13:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-01T15:13:56', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '2ca445f9-23a0-4304-99e7-1151341e00a6'	System	01 Nov 2020 20:13:59
User entered '01 Nov 2020 15:13'	System	01 Nov 2020 20:13:59

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	27 Oct 2020 13:53:30
User entered 'Day 7'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:33:25', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '356d4b0e-8d9f-4bd4-b56f-4541e373ce6f'	System	02 Nov 2020 23:34:20
User entered 'No interference with activity (1)'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:33:46', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '356d4b0e-8d9f-4bd4-b56f-4541e373ce6f'	System	02 Nov 2020 23:34:20
User entered 'No interference with activity (1)'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:33:50', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '356d4b0e-8d9f-4bd4-b56f-4541e373ce6f'	System	02 Nov 2020 23:34:20
User entered 'None (0)'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:33:55', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '356d4b0e-8d9f-4bd4-b56f-4541e373ce6f'	System	02 Nov 2020 23:34:20
User entered 'None (0)'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:33:59', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '356d4b0e-8d9f-4bd4-b56f-4541e373ce6f'	System	02 Nov 2020 23:34:20
User entered 'None (0)'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:34:03', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '356d4b0e-8d9f-4bd4-b56f-4541e373ce6f'	System	02 Nov 2020 23:34:20
User entered 'None (0)'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:34:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '356d4b0e-8d9f-4bd4-b56f-4541e373ce6f'	System	02 Nov 2020 23:34:20
User entered 'No (N)'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-02T18:34:18', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '356d4b0e-8d9f-4bd4-b56f-4541e373ce6f'	System	02 Nov 2020 23:34:20
User entered '02 Nov 2020 18:34'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 13:53:30

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	02 Nov 2020 23:34:20
User entered 'Day 8'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:57:16

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	02 Nov 2020 23:34:20
User entered 'Day 9'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:57:16

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	02 Nov 2020 23:34:20
User entered 'Day 8'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	02 Nov 2020 23:34:20
User entered 'Day 9'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:57:16

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	02 Nov 2020 23:34:20
User entered 'Day 8'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
Data entry locked.	System	02 Nov 2020 23:34:20
User entered 'Day 9'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:57:16

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 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 23:34:20

US3822443

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:57:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:28:48
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 23:34:20

US3822443

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:26

US3822443

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '3 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:26

US3822443

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:26

US3822443

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:26

US3822443

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:29

US3822443

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	02 Dec 2020 16:37:29

US3822443

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:38

US3822443

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:38

US3822443

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:38

US3822443

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:38

US3822443

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:42

US3822443

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	02 Dec 2020 16:37:42

US3822443

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:59

US3822443

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:59

US3822443

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:59

US3822443

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:37:59

US3822443

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:02

US3822443

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	02 Dec 2020 16:38:02

US3822443

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:17

US3822443

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:17

US3822443

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:17

US3822443

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'VISIT3'	System	02 Dec 2020 16:38:17

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '09:55'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '23 Nov 2020 09:55'	System	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '72'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'bpm'	System	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '20'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'breaths/min'	System	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '128'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 11:01:38
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI this is NCS' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 18:29:14
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Dec 2020 16:38:40
User entered '55'	(b) (4), (b) (6)	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'mmHg'	System	02 Dec 2020 16:38:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:39:14

US3822443

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:39:14

US3822443

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:39:37

US3822443

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:39:37

US3822443

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:22
User entered '09:55'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:39:37

US3822443

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '23 Nov 2020 09:55'	System	02 Dec 2020 16:39:37

US3822443

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:39:40

US3822443

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	02 Dec 2020 16:39:40

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-28T17:27:15', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '55d2cc94-dcef-4c0b-a054-9b7296618a5c'	System	28 Nov 2020 22:28:00
User entered 'No (N)'	System	28 Nov 2020 22:28:00

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-28T17:26:03', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '55d2cc94-dcef-4c0b-a054-9b7296618a5c'	System	28 Nov 2020 22:28:00
User entered 'No (N)'	System	28 Nov 2020 22:28:00

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-11-28T17:27:57', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '55d2cc94-dcef-4c0b-a054-9b7296618a5c' User entered '28 Nov 2020 17:27:57'	System	28 Nov 2020 22:28:00
	System	28 Nov 2020 22:28:00

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-02T20:22:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd5f32c7c-34fe-42a2-92ad-31ca77abf832'	System	03 Dec 2020 01:23:37
User entered 'No (N)'	System	03 Dec 2020 01:23:37

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-02T20:22:46', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd5f32c7c-34fe-42a2-92ad-31ca77abf832'	System	03 Dec 2020 01:23:37
User entered 'No (N)'	System	03 Dec 2020 01:23:37

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-02T20:23:29', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd5f32c7c-34fe-42a2-92ad-31ca77abf832'	System	03 Dec 2020 01:23:37
User entered '02 Dec 2020 20:23:29'	System	03 Dec 2020 01:23:37

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-12T10:10:04', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '366f8edb-2407-4112-9c50-de11fb728580'	System	12 Dec 2020 15:10:24
User entered 'No (N)'	System	12 Dec 2020 15:10:24

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-12T10:10:11', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '366f8edb-2407-4112-9c50-de11fb728580'	System	12 Dec 2020 15:10:24
User entered 'No (N)'	System	12 Dec 2020 15:10:24

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-12T10:10:19', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '366f8edb-2407-4112-9c50-de11fb728580' User entered '12 Dec 2020 10:10:19'	System	12 Dec 2020 15:10:24
	System	12 Dec 2020 15:10:24

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-16T08:31:25', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd72ad592-dc45-4286-be20-e3f4073d7926'	System	16 Dec 2020 13:32:37
User entered 'No (N)'	System	16 Dec 2020 13:32:37

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-16T08:31:36', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd72ad592-dc45-4286-be20-e3f4073d7926'	System	16 Dec 2020 13:32:37
User entered 'No (N)'	System	16 Dec 2020 13:32:37

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-16T08:32:30', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'd72ad592-dc45-4286-be20-e3f4073d7926' User entered '16 Dec 2020 08:32:30'	System	16 Dec 2020 13:32:37
	System	16 Dec 2020 13:32:37

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-23T08:30:30', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '4fa85059-05f6-4379-8813-08b2b19ff93e'	System	23 Dec 2020 13:31:45
User entered 'Yes (Y)'	System	23 Dec 2020 13:31:45

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-23T08:29:26', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '4fa85059-05f6-4379-8813-08b2b19ff93e'	System	23 Dec 2020 13:31:45
User entered 'No (N)'	System	23 Dec 2020 13:31:45

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-23T08:29:36', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '4fa85059-05f6-4379-8813-08b2b19ff93e'	System	23 Dec 2020 13:31:45
User entered 'No (N)'	System	23 Dec 2020 13:31:45

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-23T08:31:37', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '4fa85059-05f6-4379-8813-08b2b19ff93e'	System	23 Dec 2020 13:31:45
User entered 'No (N)'	System	23 Dec 2020 13:31:45

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-23T08:31:41', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '4fa85059-05f6-4379-8813-08b2b19ff93e'	System	23 Dec 2020 13:31:45
User entered '23 Dec 2020 08:31:41'	System	23 Dec 2020 13:31:45

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-31T13:40:09', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '5d6ef3dd-3c62-4d60-803b-bc028a5e584e'	System	31 Dec 2020 18:40:30
User entered 'No (N)'	System	31 Dec 2020 18:40:30

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-31T13:40:16', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '5d6ef3dd-3c62-4d60-803b-bc028a5e584e'	System	31 Dec 2020 18:40:30
User entered 'No (N)'	System	31 Dec 2020 18:40:30

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2020-12-31T13:40:26', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '5d6ef3dd-3c62-4d60-803b-bc028a5e584e'	System	31 Dec 2020 18:40:30
User entered '31 Dec 2020 13:40:26'	System	31 Dec 2020 18:40:30

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-06T09:48:01', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7b81a7fb-520c-4368-a4f0-a305761fe844'	System	06 Jan 2021 14:48:48
User entered 'Yes (Y)'	System	06 Jan 2021 14:48:48

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-06T09:48:12', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7b81a7fb-520c-4368-a4f0-a305761fe844'	System	06 Jan 2021 14:48:48
User entered 'No (N)'	System	06 Jan 2021 14:48:48

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-06T09:48:20', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7b81a7fb-520c-4368-a4f0-a305761fe844'	System	06 Jan 2021 14:48:48
User entered 'No (N)'	System	06 Jan 2021 14:48:48

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-06T09:48:32', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7b81a7fb-520c-4368-a4f0-a305761fe844'	System	06 Jan 2021 14:48:48
User entered 'No (N)'	System	06 Jan 2021 14:48:48

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-06T09:48:38', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '7b81a7fb-520c-4368-a4f0-a305761fe844'	System	06 Jan 2021 14:48:48
User entered '06 Jan 2021 09:48:38'	System	06 Jan 2021 14:48:48

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-13T17:25:34', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8ee856fc-a79e-4b02-be80-acc1d1987a70'	System	13 Jan 2021 22:26:16
User entered 'No (N)'	System	13 Jan 2021 22:26:16

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-13T17:25:45', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8ee856fc-a79e-4b02-be80-acc1d1987a70'	System	13 Jan 2021 22:26:16
User entered 'No (N)'	System	13 Jan 2021 22:26:16

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-13T17:26:09', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '8ee856fc-a79e-4b02-be80-acc1d1987a70'	System	13 Jan 2021 22:26:16
User entered '13 Jan 2021 17:26:09'	System	13 Jan 2021 22:26:16

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-20T07:01:45', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f48a9621-8549-4123-8ff4-ff017b52252a'	System	20 Jan 2021 12:02:43
User entered 'No (N)'	System	20 Jan 2021 12:02:43

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-20T07:01:57', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f48a9621-8549-4123-8ff4-ff017b52252a'	System	20 Jan 2021 12:02:43
User entered 'No (N)'	System	20 Jan 2021 12:02:43

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-20T07:02:36', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f48a9621-8549-4123-8ff4-ff017b52252a' User entered '20 Jan 2021 07:02:36'	System	20 Jan 2021 12:02:43
	System	20 Jan 2021 12:02:43

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-27T09:53:03', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f7d3dcdd-086e-498f-9d7b-f360860f15cc'	System	27 Jan 2021 14:54:59
User entered 'No (N)'	System	27 Jan 2021 14:54:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-27T09:54:43', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f7d3dcdd-086e-498f-9d7b-f360860f15cc'	System	27 Jan 2021 14:54:59
User entered 'No (N)'	System	27 Jan 2021 14:54:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-01-27T09:54:54', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: 'f7d3dcdd-086e-498f-9d7b-f360860f15cc'	System	27 Jan 2021 14:54:59
User entered '27 Jan 2021 09:54:54'	System	27 Jan 2021 14:54:59

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-02-03T12:34:55', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '91321e4b-a19c-4ca1-ad5e-4efa8c422cb9'	System	03 Feb 2021 17:35:19
User entered 'No (N)'	System	03 Feb 2021 17:35:19

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Have you been exposed to someone with 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)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-02-03T12:35:07', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '91321e4b-a19c-4ca1-ad5e-4efa8c422cb9'	System	03 Feb 2021 17:35:19
User entered 'No (N)'	System	03 Feb 2021 17:35:19

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aaf0d5c0e4d936f4)', Time: '2021-02-03T12:35:15', User OID: 'PatientReportedOutcome (US3822443)', ODM File OID: '91321e4b-a19c-4ca1-ad5e-4efa8c422cb9'	System	03 Feb 2021 17:35:19
User entered '03 Feb 2021 12:35:15'	System	03 Feb 2021 17:35:19

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

Have you been exposed to someone with 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)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 11:00:58

US3822443

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:00:58
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 11:00:58

US3822443

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 00:11:34

US3822443

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '22 Dec 2020'	Kelly Woodell (b) (4)	13 Jan 2021 00:11:34

US3822443

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	13 Jan 2021 00:11:34

US3822443

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Kelly Woodell (b) (4)	13 Jan 2021 00:11:34

US3822443

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 00:11:40

US3822443

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	13 Jan 2021 00:11:40

US3822443

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	23 Feb 2021 15:17:08

US3822443

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '26 Jan 2021'	Kelly Woodell (b) (4)	23 Feb 2021 15:17:08

US3822443

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	23 Feb 2021 15:17:08

US3822443

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Kelly Woodell (b) (4)	23 Feb 2021 15:17:08

US3822443

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Kelly Woodell (b) (4)	23 Feb 2021 15:17:11

US3822443

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	23 Feb 2021 15:17:11

US3822443

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

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Jan 2021 20:24:37

US3822443

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

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14 Jan 2021'	Kelly Woodell (b) (4)	19 Jan 2021 20:24:37

US3822443

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

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	19 Jan 2021 20:24:37

US3822443

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

Form: Visit Date

Generated On: 10 Jun 2021 09:57:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 20:24:37

US3822443

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14 Jan 2021'	(b) (4) Kelly Woodell (b) (4) (b) (4)	19 Jan 2021 20:24:47

US3822443

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[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 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:18:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:21:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:03:35

US3822443

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	19 Jan 2021 20:24:47

US3822443

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 17:40:59
	Christina Kennelly (b) (4)	12 Apr 2021 00:18:43
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Subject was unblinded under A6,' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:21:55
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 15:21:29
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	08 Apr 2021 14:52:08
	System	06 Mar 2021 20:03:35

US3822443

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:31:36
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User closed query 'Per CDM RQ: Response noted. However this field is for the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:30:46
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 10:30:42
Query 'Per CDM RQ: Response noted. However this field is for the date of unblinding in IRT. Please reconcile. Thank you' answered with 'Query resolved. Data has been updated' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:12:00
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 15:07:44
User opened query 'Per CDM RQ: Response noted. However this field is for the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:01:15
User closed query 'Per CDM RQ: Response noted. However this field is for the date of unblinding in IRT. Please reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:01:15
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Subject was scheduled for the visit prior to being unblinded. The subject was unblinded the evening prior to the their initially scheduled visit. They were not notified of their randomization assignment until after signing the amendment 6 ICF and requesting to be unblinded. ' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 17:40:25
Query 'Per CDM RQ: Response noted. However this field is for the date of unblinding in IRT. Please reconcile. Thank you.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 17:40:15
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	19 Apr 2021 17:40:10

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 17:40:10
User entered '04 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 17:40:10
User opened query 'Per CDM RQ: Response noted. However this field is for the date of unblinding in IRT. Please reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:41:03
User closed query 'Per CDM, per Sponsor Review: Per IRT, subject was unblinded on 13JAN2021. Please review and reconcile.	(b) (4), (b) (6)	16 Apr 2021 17:41:03
' (Site from DM).		
Query 'Per CDM, per Sponsor Review: Per IRT, subject was unblinded on 13JAN2021. Please review and reconcile.	(b) (4), (b) (6)	08 Apr 2021 17:18:26
' answered with 'Subject in clinic unblinding visit was 14JAN2021' (Site from DM).		
User opened query 'Per CDM, per Sponsor Review: Per IRT, subject was unblinded on 13JAN2021. Please review and reconcile.	(b) (4), (b) (6)	08 Apr 2021 16:18:03
' (Site from DM).		
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14 Jan 2021'	(b) (4) Kelly Woodell (b) (4) (b) (4)	19 Jan 2021 20:24:47

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	19 Jan 2021 20:24:47

US3822443

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 15:38:56
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	19 Jan 2021 20:24:47
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 15:38:56
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	19 Jan 2021 20:24:47
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	19 Jan 2021 20:24:47

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	19 Jan 2021 20:24:47

US3822443

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:43:18
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	19 Jan 2021 20:24:47

US3822443

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Jan 2021 20:25:00

US3822443

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14 Jan 2021'	Kelly Woodell (b) (4)	19 Jan 2021 20:25:00

US3822443

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14:26'	Kelly Woodell (b) (4)	19 Jan 2021 20:25:00

US3822443

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '14 Jan 2021 14:26'	System	19 Jan 2021 20:25:00

US3822443

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:57:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Jan 2021 20:25:08

US3822443

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14 Jan 2021'	Kelly Woodell (b) (4)	19 Jan 2021 20:25:08

US3822443

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:57:16

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14:37'	Kelly Woodell (b) (4)	19 Jan 2021 20:25:08

US3822443

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:57:16

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '14 Jan 2021 14:37'	System	19 Jan 2021 20:25:08

US3822443

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:57:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Please ensure to add AE of Swollen Feet to EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:36:51
Query 'Please ensure to add AE of Swollen Feet to EDC.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 18:23:50
User opened query 'Please ensure to add AE of Swollen Feet to EDC.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:35:30
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:27:07
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:21:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain in arm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:23:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:23:56
Data point term sent to Coder	System	10 Dec 2020 23:23:33
User entered 'arm pain'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '14 Nov 2020'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 23:23:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 23:23:09
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:23:09
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 23:22:58
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '15 Nov 2020'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Not Applicable (NOT APPLICABLE)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '1'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '0'	System	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '0'	System	10 Dec 2020 23:22:58

US3822443

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:23
User entered 'USA-US126-2020-mRNA-1273-P301000012'	System	28 Dec 2020 13:45:19
User entered 'New'	(b) (4), (b) (6)	28 Dec 2020 13:45:19

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:38:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:38:46
Data point term sent to Coder	System	23 Dec 2020 18:38:18
User entered 'Abdominal Pain'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'No (N)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'No (N)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '04 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Please review Start and End Time in CRIO source. Please update time in EDC if applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:20:31
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 15:20:28
Query 'Please review Start and End Time in CRIO source. Please update time in EDC if applicable.' answered with 'time not required because it did not happen within 24 hours of injection' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 18:23:30
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		26 Jan 2021 18:23:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 18:23:08
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Jan 2021 18:22:50
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 18:22:50
User entered '14:00' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 18:22:50
User opened query 'Please review Start and End Time in CRIO source. Please update time in EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	26 Jan 2021 18:23:08
User entered '04 Dec 2020 14:00'	System	26 Jan 2021 18:22:50
User entered empty.	System	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'No (N)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '14 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '1'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '04 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '14 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'No (N)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '0'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Dec 2020 18:38:40
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Dec 2020 18:38:07
User entered '0'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 18:38:40
User entered '0'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 18:38:40
User entered '0'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:27:40
User closed query 'PV Query: Please confirm if nausea and vomiting meet requirements for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:48:52
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:48:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:48:45
User closed query 'PV Query: Was the subject tested for COVID-19 during hospitalization? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:48:42
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'conmeds added ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 21:12:15
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records emailed to safety. ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 20:30:59
Query 'PV Query: Please confirm if nausea and vomiting meet requirements for separate AE/SAE reporting.' answered with 'Nausea/vomit were symptoms of diagnosis of abdominal pain ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 18:58:04

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Was the subject tested for COVID-19 during hospitalization? If yes, please provide results.' answered with 'Patient was not tested for COVID. ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 18:57:29
User opened query 'PV Query: Please confirm if nausea and vomiting meet requirements for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:50:18
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:50:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:49:53
User opened query 'PV Query: Was the subject tested for COVID-19 during hospitalization? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:49:45
User entered 'The subject was experiencing nausea and vomiting and presented to the emergency department. She was admitted for evaluation and was discharged 10 days later in stable condition.'	(b) (4), (b) (6)	23 Dec 2020 18:38:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '0'	System	23 Dec 2020 18:38:07

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of feet - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:13:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:13:54
Data point term sent to Coder	System	26 Jan 2021 18:22:27
User entered 'Swollen Feet'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '02 Dec 2020'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '08 Dec 2020'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:36:02
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'See con med log line 26' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:29:51
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:26:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '1'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:53:08
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:21:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '0'	System	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '0'	System	26 Jan 2021 18:21:51

US3822443

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:25:06
User entered 'USA-US126-2021-mRNA-1273-P301000005'	System	16 Feb 2021 16:16:05
User entered 'New'	(b) (4), (b) (6)	16 Feb 2021 16:16:05

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 12:55:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 12:55:49
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
Data point term sent to Coder	System	12 Feb 2021 15:23:30
User entered 'Right lower lobe pulmonary nodule concerning for primary lung malignancy'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per CRIO source, this is documented as a MAAE. Please review and update EDC if applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:15:10
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:15:08
Query 'Per CRIO source, this is documented as a MAAE. Please review and update EDC if applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 16:30:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 16:30:17
User opened query 'Per CRIO source, this is documented as a MAAE. Please review and update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:38:36
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:37:58
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:37:45
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:47
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:49
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:38:44
User entered '11 Jan 2021'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:38:48
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Feb 2021 15:23:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 15:23:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 15:23:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 15:23:22
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Feb 2021 15:23:22
User entered 'UK:UK' (non-conformant).	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	12 Feb 2021 15:23:40
User entered '11 Jan 2021 UK:UK' (non-conformant).	System	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:38:50
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:38:52
User entered '11 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:38:58
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:00
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 01:55:08
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Per source the cause of death is like the adverse event term.' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	23 Feb 2021 16:24:35
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 22:08:56
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:39:06
User entered '1'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:08
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:09
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:14
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:17
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:20
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:22
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:23
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:26
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:34
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:36
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:38
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User closed query 'Per DM CLR: Is this AE serious? = YES. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please update to record the corresponding treatment if applicable. Otherwise, clarify why no treatment is needed.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:03:54
Query 'Per DM CLR: Is this AE serious? = YES. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please update to record the corresponding treatment if applicable. Otherwise, clarify why no treatment is needed.' answered with 'Subject expired 11FEB2021. Cause of death most likely due to recent diagnosis of possible right lower lobe pulmonary nodule concerning for primary lung malignancy.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:51:50
User opened query 'Per DM CLR: Is this AE serious? = YES. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please update to record the corresponding treatment if applicable. Otherwise, clarify why no treatment is needed.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 18:05:37
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:41
User entered '1'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 01:55:11
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'N/A' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	23 Feb 2021 16:24:53
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 22:09:21
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:39:43
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:45
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:48
User entered 'Fatal (FATAL)'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:39:52
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
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)	25 Feb 2021 01:55:13
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 'N/A' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	23 Feb 2021 16:24:59
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 Feb 2021 22:09:29
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:39:55
User entered 'The subject's spouse called to report that the subject expired on 11-FEB-2021. The cause of death is likely the subject's recent diagnosis of possible right lower lobe pulmonary nodule concerning for primary lung malignancy. Records will be requested.'	(b) (4), (b) (6)	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	19 Feb 2021 16:30:17
User entered '0'	System	12 Feb 2021 15:23:22

US3822443

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:30:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:57:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:31:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:34:19
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 Oct 2020 15:34:19
Data point term sent to Coder User entered 'Budesonide'	System (b) (4), (b) (6)	05 Oct 2020 15:33:37 05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:47:27
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:32:43
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:34:30
User entered 'COPD'	(b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0.5'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2'	System	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:32:38

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 20:08:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:08:59
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Dec 2020 16:33:41 02 Dec 2020 16:33:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:58:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:58:16
Data point term sent to Coder User entered 'Gigoxin'	System (b) (4), (b) (6)	05 Oct 2020 15:34:39 05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:49:02
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:33:28
User entered 'Atrial fibrillation' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 16:33:22
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:35:04
User entered 'Heart rhythm'	(b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '125'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
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. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 09:34:07
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. Otherwise, clarify. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:28:20
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. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:46:21
User entered 'UN UNK 2014'	(b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:34:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Dec 2020 16:36:19
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 Dec 2020 16:36:19
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Dec 2020 16:34:44 02 Dec 2020 16:33:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:36:16
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 Oct 2020 15:36:16
Data point term sent to Coder User entered 'Diltiazem'	System (b) (4), (b) (6)	05 Oct 2020 15:35:41 05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:51:48
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:33:50
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 16:33:44
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:35:43
User entered 'HTN'	(b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '180'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:34:42

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:36:16
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 Oct 2020 15:36:16
Data point term sent to Coder	System	05 Oct 2020 15:35:43
User entered 'Duloxetine'	(b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 08:44:10
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'added in med hx' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:34:07
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:35:59
User entered 'Anxiety'	(b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '60'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2'	System	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:35:17

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 16:35:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 16:35:45
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Dec 2020 16:34:43 02 Dec 2020 16:34:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 15:38:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 15:38:24
Data point term sent to Coder User entered 'Ipratropium bromide'	System (b) (4), (b) (6)	05 Oct 2020 15:36:44 05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). 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) (4), (b) (6)	04 Dec 2020 12:03:08
Query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). 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).	(b) (4), (b) (6)	02 Dec 2020 16:34:28
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 16:34:23
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:37:04
User opened query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). 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)	01 Dec 2020 17:36:27
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:36:16
User entered 'allergies'	(b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per CDM (CLR Re-Query): Site response noted; however, please note MCG=UG (micrograms). To satisfy previous query, please review the "Dose per administration" and update appropriately. Else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 11:33:05
Query 'Per CDM (CLR Re-Query): Site response noted; however, please note MCG=UG (micrograms). To satisfy previous query, please review the "Dose per administration" and update appropriately. Else clarify. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 20:01:17
User opened query 'Per CDM (CLR Re-Query): Site response noted; however, please note MCG=UG (micrograms). To satisfy previous query, please review the "Dose per administration" and update appropriately. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:38:47
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:38:47
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:30:32
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:46:33
User entered '42'	(b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:01:12
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 14:30:25
User entered 'ug (ug)'	(b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:01:12
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 14:30:25
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2'	System	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:36:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL, PRODUCTSYNONYM: LEVALBUTEROL [LEVOSALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:56:27
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 Oct 2020 15:56:27
Data point term sent to Coder	System	05 Oct 2020 15:37:48
User entered 'Levalbuterol'	(b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0.63'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:36:55

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OTHER DRUGS FOR CONSTIPATION, PRODUCT: LINACLOTIDE, PRODUCTSYNONYM: LINZESS - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 15:40:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:40:29
Data point term sent to Coder User entered 'Linzess'	System (b) (4), (b) (6)	05 Oct 2020 15:38:51 05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 08:42:48
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'ADDED IN MED HX' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:34:42
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:37:30
User entered 'Constipation'	(b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '72'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:38:05

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	(b) (4) Coders Import (b) (4) (b) (4)	05 Oct 2020 15:40:29
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\202003.	Coders Import (b) (4) (b) (4)	05 Oct 2020 15:40:29
Data point term sent to Coders	System	05 Oct 2020 15:38:51
User entered 'Miralax'	(b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Constipation'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN Feb 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:38:37

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Dec 2020 14:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:29:43
Data point term sent to Coder	System	02 Dec 2020 16:35:45
Coding entries removed.	(b) (4), (b) (6)	02 Dec 2020 16:35:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:00:22
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 Oct 2020 16:00:22
Data point term sent to Coder	System	05 Oct 2020 15:39:52
User entered 'Montelukast'	(b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please update the indication as it is not expected to be unknown for an ongoing medication. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 09:08:16
Query 'Per DM CLR: Please update the indication as it is not expected to be unknown for an ongoing medication. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:35:20
User entered 'SHORTNESS OF BREATH, COPD' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 16:35:15
User opened query 'Per DM CLR: Please update the indication as it is not expected to be unknown for an ongoing medication. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:38:13
User entered 'UNK'	(b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '10'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:39:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\202003.	(b) (4) Coders Import (b) (4) (b) (4)	05 Oct 2020 15:40:30
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\202003.	Coders Import (b) (4) (b) (4)	05 Oct 2020 15:40:30
Data point term sent to Coders	System	05 Oct 2020 15:39:53
User entered 'Pantoprazole'	(b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 09:11:32
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'ADDED TO MED HX' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:35:34
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:38:33
User entered 'Acid reflux'	(b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '40'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:39:44

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: FORMOTEROL FUMARATE, PRODUCTSYNONYM: PERFOROMIST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:04:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:04:26
Data point term sent to Coder	System	05 Oct 2020 15:40:54
User entered 'Perforomist'	(b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '20'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2'	System	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:40:25

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:42:23
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 Oct 2020 15:42:23
Data point term sent to Coder	System	05 Oct 2020 15:41:55
User entered 'Prednisone'	(b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '5'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:40:57

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:48:23
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 Oct 2020 15:48:23
Data point term sent to Coder User entered 'Prolia'	System (b) (4), (b) (6)	05 Oct 2020 15:47:11 05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 08:40:41
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:35:49
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:39:05
User entered 'Osteoporosis'	(b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '60'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Every 6 months'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:46:24

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
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: PROVENTIL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 21:31:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:31:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Dec 2020 16:36:47 02 Dec 2020 16:36:17
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: PROVENTIL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:15:18
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 Oct 2020 16:15:18
Data point term sent to Coder User entered 'Proventil'	System (b) (4), (b) (6)	05 Oct 2020 15:48:17 05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please update the indication as it is not expected to be unknown for an ongoing medication. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:45:24
Query 'Per DM CLR: Please update the indication as it is not expected to be unknown for an ongoing medication. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:36:22
User entered 'COPD, SHORTNESS OF BREATH' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 16:36:17
User opened query 'Per DM CLR: Please update the indication as it is not expected to be unknown for an ongoing medication. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:40:04
User entered 'UNK'	(b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '90'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'every 4 hours'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:47:28

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: REVEFENACIN, PRODUCTSYNONYM: YUPELRI - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:49:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:49:27
Data point term sent to Coder User entered 'Yupelri'	System (b) (4), (b) (6)	05 Oct 2020 15:48:17 05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '175'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN Jan 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:48:14

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	02 Dec 2020 16:38:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Dec 2020 16:38:30
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Dec 2020 16:36:47 02 Dec 2020 16:36:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Oct 2020 15:50:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Oct 2020 15:50:32
Data point term sent to Coder User entered 'Mucinex DM'	System (b) (4), (b) (6)	05 Oct 2020 15:49:19 05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). 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) (4), (b) (6)	04 Dec 2020 11:46:03
Query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). 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).	(b) (4), (b) (6)	02 Dec 2020 16:36:43
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 16:36:37
User opened query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). 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)	01 Dec 2020 17:40:27
User entered 'Allergies'	(b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:48:48

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
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.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:51:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:51:21
Data point term sent to Coder User entered 'Centrum'	System (b) (4), (b) (6)	05 Oct 2020 15:50:24 05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:49:50

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:52:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:52:28
Data point term sent to Coder	System	05 Oct 2020 15:51:27
User entered 'Vitamin E'	(b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '450'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:51:04

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:53:17
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 Oct 2020 15:53:17
Data point term sent to Coder	System	05 Oct 2020 15:52:28
User entered 'Vitamin D3'	(b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '5000'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:51:43

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: CALTRATE [CALCIUM CARBONATE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:53:17
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 Oct 2020 15:53:17
Data point term sent to Coder	System	05 Oct 2020 15:52:28
User entered 'Caltrate'	(b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '600'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:52:12

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN A AND D IN COMBINATION, PRODUCT: COD-LIVER OIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 17:04:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:04:33
Data point term sent to Coder	System	05 Oct 2020 15:53:32
User entered 'Cod Liver Oil'	(b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:52:58

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	05 Oct 2020 15:54:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	05 Oct 2020 15:54:21
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	05 Oct 2020 15:53:33 05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '81'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	05 Oct 2020 15:53:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:56:26
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 Oct 2020 15:56:26
Data point term sent to Coder User entered 'Tdap'	System (b) (4), (b) (6)	05 Oct 2020 15:55:37 05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 May 2014'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '28 May 2014'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:55:11

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:43
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:23:01
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 Nov 2020 21:23:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:57:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:57:18
Data point term sent to Coder User entered 'Influenza'	System (b) (4), (b) (6)	05 Oct 2020 15:56:39 05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0.5'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '15 Oct 2019'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '15 Oct 2019'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:56:06

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 15:58:26
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 Oct 2020 15:58:26
Data point term sent to Coder User entered 'Pneumococcal'	System (b) (4), (b) (6)	05 Oct 2020 15:57:40 05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14 Apr 2016'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14 Apr 2016'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	05 Oct 2020 15:57:07

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 12:24:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:24:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	26 Feb 2021 14:29:39 26 Feb 2021 14:29:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 21:17:21
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 Dec 2020 21:17:21
Data point term sent to Coder User entered 'lasix'	System Krishna Shah (b) (4) (b) (4)	30 Dec 2020 20:54:19 30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'ABDOMINAL PAIN and SWOLLEN FEET' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:29:19
User entered 'abdominal pain'	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '40'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Intravenous (INTRAVENOUS)'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '4 Dec 2020'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '5 Dec 2020' reason for change: Data Entry Error	Krishna Shah (b) (4)	30 Dec 2020 20:54:14
User entered '6 Dec 2020'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	30 Dec 2020 20:54:01

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Dec 2020 21:17:21
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 Dec 2020 21:17:21
Data point term sent to Coder	System	30 Dec 2020 21:03:30
User entered 'lasix'	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'abdominal pain'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '40'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Intravenous (INTRAVENOUS)'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '12 Dec 2020'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '12 Dec 2020'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	30 Dec 2020 21:03:22

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 11:23:07
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'Patient is deceased. I cannot confirm this' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:46:54
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:55:38
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:55:04
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:54:56

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
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)	30 Dec 2020 21:10:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 21:10:27
Data point term sent to Coder	System	30 Dec 2020 21:09:34
User entered 'metoprolol'	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'hypertension'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '12.5'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'twice daily (BID)'	(b) (4) Krishna Shah (b) (4) (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '6 Dec 2020'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2'	System	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	30 Dec 2020 21:09:26

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Dec 2020 21:12:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 21:12:21
Data point term sent to Coder	System	30 Dec 2020 21:11:35
User entered 'Oxygen'	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'COPD'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '2'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Other (OTHER)'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'liters'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'as needed (PRN)'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '4 Dec 2020'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Yes (Y)'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered empty.	System	30 Dec 2020 21:10:46

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening COPD should be recorded, and update con med indication or provide clarification.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 11:23:59
' (Site from DM).		
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening COPD should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	23 Feb 2021 14:48:11
' answered with 'Patient is deceased. I cannot confirm this. ' (Site from DM).		
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening COPD should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	23 Feb 2021 06:56:38
' (Site from DM).		
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 21:13:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 21:13:24
Data point term sent to Coder	System	30 Dec 2020 21:12:36
User entered 'Prednisone'	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'COPD'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '45'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'mg (mg)'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'once daily (QD)'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Oral (ORAL)'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '14 Dec 2020'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '0'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '19 Dec 2020'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	Krishna Shah (b) (4)	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '1'	System	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:57:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '804 (804)'	System	30 Dec 2020 21:12:03

US3822443

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:57:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:42:27
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User closed query 'Per ETRTR: According to SAE "Abdominal Pain" CRF page, Concomitant procedure was performed for SAE. Please confirm whether procedure was done or not and reconcile with SAE page if required, thanks.' (Site from CRA).	Kelly Woodell (b) (4)	02 Mar 2021 16:25:54
Query 'Per ETRTR: According to SAE "Abdominal Pain" CRF page, Concomitant procedure was performed for SAE. Please confirm whether procedure was done or not and reconcile with SAE page if required, thanks.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 17:57:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 20:28:06
User opened query 'Per ETRTR: According to SAE "Abdominal Pain" CRF page, Concomitant procedure was performed for SAE. Please confirm whether procedure was done or not and reconcile with SAE page if required, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:26:46
User entered 'No (N)'	Krishna Shah (b) (4)	14 Jan 2021 21:49:02
	(b) (4)	10 Dec 2020 23:23:45

US3822443

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:57:16

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:04:34

US3822443

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:57:16

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Death (DEATH)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:04:34

US3822443

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:57:16

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:04:34

US3822443

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:57:16

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:47:48
User closed query 'Per CDM: "Right Lower lobe pulmonary nodule concerning for primary lung malignancy" is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:27
Query 'Per CDM: "Right Lower lobe pulmonary nodule concerning for primary lung malignancy" is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 20:04:15
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 20:03:59
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:03:59
User opened query 'Per CDM: "Right Lower lobe pulmonary nodule concerning for primary lung malignancy" is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 16:36:02
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'Unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:04:34

US3822443

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:57:16

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:04:34

US3822443

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:57:16

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:04:34

US3822443

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:57:16

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:04:34

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

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Generated On: 10 Jun 2021 09:57:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'USA-US126-2020-MRNA-1273-P301000012'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Yes (Y)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Yes (Y)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Christina'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Kennelly'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:59
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 18:28:24
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
Query 'Please complete all address fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:34:52
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:34:34
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
User closed query 'No updates were made to address. Please enter address in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:46:45
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:44
Query 'No updates were made to address. Please enter address in EDC.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 16:00:58
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
User opened query 'No updates were made to address. Please enter address in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:17:34
User closed query 'Please complete each individual address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:17:34
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
Query 'Please complete each individual address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:37:54
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

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Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: [Street](#)

Audit	User	Time (GMT)
User opened query 'Please complete each individual address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:26:47

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:47
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

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Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:48
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

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Folder: SAE USA-US126-2020-MRNA-1273-P301000012

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:50
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

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Folder: SAE USA-US126-2020-MRNA-1273-P301000012

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[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:52
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:49:07
User entered 'US'	System	28 Dec 2020 13:45:57

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Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '3'	System	27 Jan 2021 15:35:39
User entered '2'	System	04 Jan 2021 17:49:44
User entered '1'	System	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'USA-US126-2020-MRNA-1273-P301000012'	System	28 Dec 2020 13:45:19

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Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Yes (Y)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Yes (Y)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Christina'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Kennelly'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:59
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 18:28:24
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
Query 'Please complete all address fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:34:52
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:34:34
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
User closed query 'No updates were made to address. Please enter address in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:46:45
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:44
Query 'No updates were made to address. Please enter address in EDC.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 16:00:58
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
User opened query 'No updates were made to address. Please enter address in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:17:34
User closed query 'Please complete each individual address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:17:34
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
Query 'Please complete each individual address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:37:54
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User opened query 'Please complete each individual address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:26:47

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:47
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:48
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:50
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:52
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:49:07
User entered 'US'	System	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '3'	System	27 Jan 2021 15:35:39
User entered '2'	System	04 Jan 2021 17:49:44
User entered '1'	System	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:57:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
User entered '28/Dec/2020 05:45'	System	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:57:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:49:07
User entered '1'	(b) (4), (b) (6)	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'USA-US126-2020-MRNA-1273-P301000012'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Yes (Y)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Yes (Y)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Christina'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Kennelly'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:59
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 18:28:24
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
Query 'Please complete all address fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:34:52
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:34:34
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
User closed query 'No updates were made to address. Please enter address in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:46:45
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:44
Query 'No updates were made to address. Please enter address in EDC.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 16:00:58
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
User opened query 'No updates were made to address. Please enter address in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:17:34
User closed query 'Please complete each individual address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:17:34
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
Query 'Please complete each individual address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:37:54
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User opened query 'Please complete each individual address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:26:47

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:47
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:48
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:50
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:52
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:49:07
User entered 'US'	System	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '3'	System	27 Jan 2021 15:35:39
User entered '2'	System	04 Jan 2021 17:49:44
User entered '1'	System	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:57:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
User entered '04/Jan/2021 17:49'	System	04 Jan 2021 17:49:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:57:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:35:30
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:26:56
User entered '1'	(b) (4), (b) (6)	04 Jan 2021 17:49:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'USA-US126-2020-MRNA-1273-P301000012'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Yes (Y)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Yes (Y)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'No (N)'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Christina'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:56
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 13:45:49
User entered 'Kennelly'	System	28 Dec 2020 13:45:19

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:59
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 18:28:24
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
Query 'Please complete all address fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:34:52
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:34:34
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
User closed query 'No updates were made to address. Please enter address in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:46:45
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:44
Query 'No updates were made to address. Please enter address in EDC.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 16:00:58
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
User opened query 'No updates were made to address. Please enter address in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:17:34
User closed query 'Please complete each individual address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:17:34
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
Query 'Please complete each individual address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:37:54
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User opened query 'Please complete each individual address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:26:47

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:47
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:48
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 19:27:06
User entered empty.	System	19 Feb 2021 17:24:40
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:34:47
DataPoint Un-verified.	System	16 Feb 2021 16:16:05
User entered empty.	System	16 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:46:50
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 16:00:47
Un-reviewed for Safety.	System	27 Jan 2021 15:35:39
User entered empty.	System	27 Jan 2021 15:35:39
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:35:30
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:37:44

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:26:52
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:49:07
User entered 'US'	System	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '3'	System	27 Jan 2021 15:35:39
User entered '2'	System	04 Jan 2021 17:49:44
User entered '1'	System	28 Dec 2020 13:45:57

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:57:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:17:49
User entered '27/Jan/2021 10:35'	System	27 Jan 2021 15:35:39

US3822443

Folder: SAE USA-US126-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:57:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:18:09
User entered '1'	(b) (4), (b) (6)	27 Jan 2021 15:35:39

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'USA-US126-2021-MRNA-1273-P301000005'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Yes (Y)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Yes (Y)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Christina'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Kennelly'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:30
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:43:00
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	23 Mar 2021 13:41:01
Signature has been broken.	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:12:47
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	(b) (4) System	19 Feb 2021 17:24:40
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4) (b) (4)	16 Feb 2021 16:48:34

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:34
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered 'Charlotte' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	System	19 Feb 2021 17:24:40
	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered 'Charlotte'	(b) (4) Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

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Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:35
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered 'NC' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	System	19 Feb 2021 17:24:40
	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered 'NC'	(b) (4) Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:38
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4)	
	Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered '28210' reason for change: Data Entry Error	(b) (4)	
	Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	(b) (4)	
	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	(b) (4)	
	System	19 Feb 2021 17:24:40
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered '28210'	(b) (4)	
	Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'US'	System	16 Feb 2021 16:17:59

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2'	System	19 Feb 2021 17:24:40
User entered '1'	System	16 Feb 2021 16:17:59

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'USA-US126-2021-MRNA-1273-P301000005'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Yes (Y)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Yes (Y)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Christina'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Kennelly'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:30
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:43:00
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	23 Mar 2021 13:41:01
Signature has been broken.	Kelly Woodell (b) (4) (b) (4)	23 Mar 2021 13:40:54
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	23 Mar 2021 13:40:54
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:12:47
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	System	19 Feb 2021 17:24:40
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4) (b) (4)	16 Feb 2021 16:48:34

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:34
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered 'Charlotte' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	System	19 Feb 2021 17:24:40
	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered 'Charlotte'	(b) (4) Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:35
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered 'NC' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	System	19 Feb 2021 17:24:40
	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered 'NC'	(b) (4) Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:38
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4)	
	Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered '28210' reason for change: Data Entry Error	(b) (4)	
	Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
Un-reviewed for Safety.	System	19 Feb 2021 17:24:40
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 17:24:26
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
	(b) (4)	
User entered '28210'	Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'US'	System	16 Feb 2021 16:17:59

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2'	System	19 Feb 2021 17:24:40
User entered '1'	System	16 Feb 2021 16:17:59

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:57:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered '16/Feb/2021 11:17'	System	16 Feb 2021 16:17:59

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:57:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered '1'	(b) (4), (b) (6)	16 Feb 2021 16:17:59

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'USA-US126-2021-MRNA-1273-P301000005'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Yes (Y)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Yes (Y)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'No (N)'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Christina'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'Kennelly'	System	16 Feb 2021 16:16:05

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:30
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:43:00
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	23 Mar 2021 13:41:01
Signature has been broken.	Kelly Woodell (b) (4) (b) (4)	23 Mar 2021 13:40:54
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	23 Mar 2021 13:40:54
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:12:47
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	System	19 Feb 2021 17:24:40
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4) (b) (4)	16 Feb 2021 16:48:34

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:34
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered 'Charlotte' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	System	19 Feb 2021 17:24:40
	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered 'Charlotte'	(b) (4) Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

US3822443

Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:35
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered 'NC' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	System	19 Feb 2021 17:24:40
	(b) (4), (b) (6)	19 Feb 2021 17:24:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
User entered 'NC'	(b) (4) Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

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Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:38
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:40:28
Signature has been broken.	(b) (4)	
	Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User entered '28210' reason for change: Data Entry Error	(b) (4)	
	Kelly Woodell (b) (4)	23 Mar 2021 13:40:54
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
	(b) (4)	
Un-reviewed for Safety.	System	19 Feb 2021 17:24:40
DataPoint Un-verified.	System	19 Feb 2021 17:24:40
User entered empty.	System	19 Feb 2021 17:24:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 17:24:26
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:36:26
	(b) (4)	
User entered '28210'	Kelly Woodell (b) (4)	16 Feb 2021 16:48:34
	(b) (4)	

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Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:36:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 16:20:03
User entered 'US'	System	16 Feb 2021 16:17:59

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Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
User entered '2'	System	19 Feb 2021 17:24:40
User entered '1'	System	16 Feb 2021 16:17:59

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Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:57:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 14:13:16
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '19/Feb/2021 12:24'	(b) (4) System	19 Feb 2021 17:24:40

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Folder: SAE USA-US126-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:57:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 14:13:19
User signature succeeded.	Christina Kennelly (b) (4)	08 Mar 2021 13:19:18
User entered '1'	(b) (4), (b) (6)	19 Feb 2021 17:24:40