

US3222315 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:08:31

All time stamps listed in this document are displayed in GMT

US3222315

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

[Participant ID](#)

US3222315

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

US3222315

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Date of Informed Consent (dd MMM yyyy)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	DIABETES, TYPE II
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	ALLERGIES, SEASONAL
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222315

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	ALLERGIES, MORPHINE
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	ALLERGY, CODEINE
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	ALLERGY, HYDROCODONE
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	ALLERGY TO DICLOFENAC
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	INTRAOCCULAR LENS IMPLANTS-BILATERAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	BILATERAL CARPAL TUNNEL SYNDROME
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	BILATERAL CARPAL TUNNEL RELEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	LEFT SHOULDER REPLACED
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	OSTEOARTHRITIS LEFT SHOULDER
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	HYPERTENSION
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 (18)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	RENAL CALCULI
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

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

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222315

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	OSTEOARTHRITIS - RIGHT HIP
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222315

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222315

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:05
Height (xxx.x)	170.0 cm
Weight (xxx.x)	81.6 kg
BMI (xxx.x)	28.23529 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)	

US3222315

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Date of assessment (dd MMM yyyy) 24 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2005

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

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 RETIRED

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) 20 Feb 2021 14:56:04

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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) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 188030

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) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

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) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

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)	24 AUG 2020
Time of assessment (00:00-23:59)	16:10 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:10
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

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)	24 AUG 2020
Time of assessment (00:00-23:59)	17:33 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 17:33
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 16:58 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 16:58

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	24 AUG 2020
Collection time (00:00-23:59)	16:40 (24 HR)
Collection date and time (derived)	24 AUG 2020 16:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:41	24 AUG 2020 16:41
Nasopharyngeal Swab 2	No		

US3222315

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 AUG 2020 17:18

PC Close Date & Time

24 AUG 2020 19:48

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

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 98.6 °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	25 AUG 2020 06:18
PC Open Date & Time	24 AUG 2020 20:43
PC Close Date & Time	25 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 06:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

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

96.5 °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 AUG 2020 08:24

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 28 AUG 2020 06:40

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 11:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

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

30 AUG 2020 09:34

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

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

98.6 °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

31 AUG 2020 07:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 AUG 2020 17:18

PC Close Date & Time

24 AUG 2020 19:48

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 06:18

PC Open Date & Time

24 AUG 2020 20:43

PC Close Date & Time

25 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 2
Please record - PAIN AT INJECTION SITE.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
PC Time Stamp	26 AUG 2020 06:13
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 08:25

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE. Please select one response below	None ☒
	Does not interfere with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
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	28 AUG 2020 06:41
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 11:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 09:36

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 07:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

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 ☐

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

24 AUG 2020 17:18

PC Close Date & Time

24 AUG 2020 19:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

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 ☐

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

24 AUG 2020 20:43

PC Close Date & Time

25 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	26 AUG 2020 06:13
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

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)

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	27 AUG 2020 08:25
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	28 AUG 2020 06:41
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

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)

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	29 AUG 2020 11:09
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	30 AUG 2020 09:36
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	31 AUG 2020 07:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:08:31

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 01 SEP 2020 09:06

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:08:31

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

01 SEP 2020 09:06

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

01 SEP 2020 09:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 SEP 2020 07:27

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 03 SEP 2020 06:18

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 04 SEP 2020 09:36

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 05 SEP 2020 07:37

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

06 SEP 2020 09:15

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

06 SEP 2020 12:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 07 SEP 2020 12:33

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

09 SEP 2020 06:08

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

10 SEP 2020 14:09

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 SEP 2020 09:07

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 02 SEP 2020 07:27

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 03 SEP 2020 06:18

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 04 SEP 2020 09:37

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 SEP 2020 07:37

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 06 SEP 2020 09:15

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 06 SEP 2020 12:10

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 07 SEP 2020 12:34

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 SEP 2020 06:08

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 10 SEP 2020 14:09

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 SEP 2020 09:07
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	02 SEP 2020 07:27
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 SEP 2020 06:18
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	04 SEP 2020 09:37
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 SEP 2020 07:37
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	06 SEP 2020 09:15
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	06 SEP 2020 12:10
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	07 SEP 2020 12:34
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 SEP 2020 06:08
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 SEP 2020 14:09
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 SEP 2020

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

Comments THREE CALL ATTEMPTS WERE
MADE: 7SEP, 8SEP, AND 9SEP
If Contact Not Made, please provide Comments WITH NO SUCCESS

US3222315

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments CALLS ATTEMPTED WITH
MESSAGES LEFT AND NO
If Contact Not Made, please provide Comments RETURN CALLS ON SEP. 14,15,16
AND 19.

US3222315

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 11:32
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	13:04 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 13:04
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3222315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

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.

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 22 SEP 2020

What was the treatment time? (00:00-23:59) 12:34 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 12:34

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

US3222315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

11:45 (24 HR)

Collection date and time (derived)

22 SEP 2020 11:45

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:48	22 SEP 2020 11:48
Nasopharyngeal Swab 2	No		

US3222315

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 13:13

PC Open Date & Time

22 SEP 2020 12:54

PC Close Date & Time

22 SEP 2020 15:24

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	23 SEP 2020 07:52
PC Open Date & Time	22 SEP 2020 16:19
PC Close Date & Time	23 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 14:01

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 12:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:10

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

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 ☒

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 07:40

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 06:01

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 13:13

PC Open Date & Time

22 SEP 2020 12:54

PC Close Date & Time

22 SEP 2020 15:24

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 07:53

PC Open Date & Time

22 SEP 2020 16:19

PC Close Date & Time

23 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 14:01

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 12:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 12:11

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 07:40

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 06:01

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

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 ☐

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 13:14
PC Open Date & Time	22 SEP 2020 12:54
PC Close Date & Time	22 SEP 2020 15:24

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

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 ☐

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 07:54
PC Open Date & Time	22 SEP 2020 16:19
PC Close Date & Time	23 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	23 SEP 2020 14:01
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	25 SEP 2020 12:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

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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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	26 SEP 2020 12:11
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

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)

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US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	28 SEP 2020 07:41
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

Yes ☐	
PC Time stamp	29 SEP 2020 06:02
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 29 SEP 2020 12:00

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 30 SEP 2020 16:46

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 01 OCT 2020 20:35

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 OCT 2020 23:59

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 03 OCT 2020 13:47

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 04 OCT 2020 12:06

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 05 OCT 2020 12:03

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 06 OCT 2020 23:59

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 07 OCT 2020 13:44

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 08 OCT 2020 12:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 09 OCT 2020 12:27

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 10 OCT 2020 12:00

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 OCT 2020 12:00

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp	13 OCT 2020 00:00

PC Open Date & Time	12 OCT 2020 12:00

PC Close Date & Time	13 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 OCT 2020 12:00

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 14 OCT 2020 12:01

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 OCT 2020 13:21

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 OCT 2020 12:01

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 OCT 2020 08:29

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 OCT 2020 12:44

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 OCT 2020 06:00

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 OCT 2020 12:01

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 OCT 2020 23:59

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 OCT 2020 08:48

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 OCT 2020 23:59

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 33

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 OCT 2020 13:07

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 34

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 25 OCT 2020 12:00

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 35

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 OCT 2020 13:18

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 36

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 27 OCT 2020 16:37

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 37

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 28 OCT 2020 12:00

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 38

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 30 OCT 2020 08:01

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 39

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 30 OCT 2020 12:31

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 40

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

01 NOV 2020 07:48

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 41

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 01 NOV 2020 12:54

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 42

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 43

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 04 NOV 2020 00:00

PC Open Date & Time 03 NOV 2020 12:00

PC Close Date & Time 04 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 44

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

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

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 45

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 29 SEP 2020 12:00

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 SEP 2020 16:46

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 OCT 2020 20:35

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 02 OCT 2020 23:59

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 03 OCT 2020 13:47

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	04 OCT 2020 12:06

PC Open Date & Time	04 OCT 2020 12:00

PC Close Date & Time	05 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 OCT 2020 12:03

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 06 OCT 2020 23:59

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 07 OCT 2020 13:44

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	08 OCT 2020 12:00

PC Open Date & Time	08 OCT 2020 12:00

PC Close Date & Time	09 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 OCT 2020 12:27

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 10 OCT 2020 12:02

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 11 OCT 2020 12:01

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 OCT 2020 00:00

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 OCT 2020 12:01

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 14 OCT 2020 12:02

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 15 OCT 2020 13:21

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 OCT 2020 12:01

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 OCT 2020 08:30

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	18 OCT 2020 12:44

PC Open Date & Time	18 OCT 2020 12:00

PC Close Date & Time	19 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	20 OCT 2020 06:01

PC Open Date & Time	19 OCT 2020 12:00

PC Close Date & Time	20 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 OCT 2020 12:01

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 OCT 2020 00:00

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 OCT 2020 08:48

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 OCT 2020 23:59

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 33

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 OCT 2020 13:07

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 34

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 25 OCT 2020 12:00

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 35

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 OCT 2020 13:18

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 36

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 27 OCT 2020 16:37

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 37

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	28 OCT 2020 12:01

PC Open Date & Time	28 OCT 2020 12:00

PC Close Date & Time	29 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 38

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 OCT 2020 08:01

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 39

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 OCT 2020 12:31

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 40

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

01 NOV 2020 07:48

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 41

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 NOV 2020 12:54

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 42

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 43

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 04 NOV 2020 00:00

PC Open Date & Time 03 NOV 2020 12:00

PC Close Date & Time 04 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 44

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

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

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 45

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	29 SEP 2020 12:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	30 SEP 2020 16:46
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 OCT 2020 20:35
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 OCT 2020 00:00
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 OCT 2020 13:48
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

04 OCT 2020 12:06

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 OCT 2020 12:03
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	07 OCT 2020 00:00
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	07 OCT 2020 13:45
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 OCT 2020 12:01
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 OCT 2020 12:27
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 OCT 2020 12:02
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 OCT 2020 12:01
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	13 OCT 2020 00:00
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	13 OCT 2020 12:01
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 OCT 2020 12:02
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 OCT 2020 13:22
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 OCT 2020 12:01
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 OCT 2020 08:30
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 OCT 2020 12:45
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 OCT 2020 06:01
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 OCT 2020 12:01
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	22 OCT 2020 00:00
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	23 OCT 2020 08:48
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	24 OCT 2020 00:00
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 33
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	24 OCT 2020 13:07
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 34
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	25 OCT 2020 12:00
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 35
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	26 OCT 2020 13:18
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 36
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	27 OCT 2020 16:37
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 37
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	28 OCT 2020 12:01
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 38
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	30 OCT 2020 08:01
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 39
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	30 OCT 2020 12:32
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 40
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 NOV 2020 07:48
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 41
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 NOV 2020 12:54
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 42
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 43
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	04 NOV 2020 00:00
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 44
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

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 45
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3222315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222315

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

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.

US3222315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	08:22 (24 HR)
Collection date and time (derived)	22 OCT 2020 08:22

US3222315

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:56:04

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 OCT 2020 13:08:48
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 00:54:45

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 07:01:02
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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 ☐

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

Date and time of submission

21 NOV 2020 06:11:08

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 103

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

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 159

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

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 173

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

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 201

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

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 208

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

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 215

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

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 236

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

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

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13 MAR 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

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20 MAR 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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23 MAR 2022 00:01

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27 MAR 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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03 APR 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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06 APR 2022 00:01

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10 APR 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 600

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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17 APR 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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20 APR 2022 00:01

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24 APR 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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27 APR 2022 00:01

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01 MAY 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

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08 MAY 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

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22 MAY 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

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29 MAY 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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05 JUN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

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17 JUL 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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24 JUL 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

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31 JUL 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

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07 AUG 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

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21 AUG 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 775

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

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

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

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

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3222315

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:08:31

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

US3222315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:52:28

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

SPOKE WITH SUBJECT, NO NEW
MEDICATIONS OR ILLNESSES.

If Contact Not Made, please provide Comments

(b) (6)

US3222315

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:12:40

Generated On: 09 Jun 2021 16:08:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:12:40

Generated On: 09 Jun 2021 16:08:31

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:12:40

Generated On: 09 Jun 2021 16:08:31

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.

US3222315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

23 MAR 2021 11:10

US3222315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 APR 2021

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments 4-19-21 @ 16:14 LVM/ (b) (6)
4-20-21 @ 11:30 LVM/ (b) (6)
If Contact Not Made, please provide Comments 4-21-21 @ 08:00 LVM/ (b) (6)

US3222315

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222315

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:08:31

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 ☐

US3222315

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:08:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	12 JAN 2021

Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒

Folder OID	UNBLND_DECIDE

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Date of updated informed consent (dd MMM yyyy)	12 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)	12 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	1
Continuing with mRNA-1273	1

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Height	
Weight	
BMI (xxx.x)	

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 09:36
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:56
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 10:26 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 10:26

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	09:26 (24 HR)
Collection date and time (derived)	12 JAN 2021 09:26

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	09:30
Collection Date and Time (derived)	12 JAN 2021 09:30

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

THREE ATTEMPTS MADE, LEFT
VOICEMAILS, NO ANSWER OR
REPLIES MADE.

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:56:03

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?	Yes ☒	
	No ☐	
Continuing Flag		1
OLD29 Placebo Flag		1

US3222315

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 FEB 2021
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 11:53
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 FEB 2021
Time of assessment (00:00-23:59)	13:47 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 13:47
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3222315

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3222315

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 08 FEB 2021

What was the treatment time? (00:00-23:59) 13:07 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 13:07

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

US3222315

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222315

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD57

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222315

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

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.

US3222315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	11:10 (24 HR)
Collection date and time (derived)	23 MAR 2021 11:10

US3222315

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

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) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

AEID	USA-US104-2020-MRNA-1273-P30 1000002
Adverse event	OSTEOARTHRITIS RIGHT HIP
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)	9 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	9 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	10 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

ELECTIVE RIGHT HIP
ARTHROPLASTY ADMITTED
TIME PER PATIENT 08:00 AM
09/SEP/2020 & DISCHARGE TIME
PER PATIENT 10:00 AM ON
10/SEP/2020.
REQUESTING MEDICAL
RECORDS. MEDICAL RECORDS
RECEIVED , ALL TEST RESULTS
ARE WITHIN NORMAL RANGE.

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) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

AEID

Adverse event

JOINT ACHES (GENERALIZED)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

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 (4)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

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 (5)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

AEID	
Adverse event	MUSCLE ACHES
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☒ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

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)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication DEGENERATIVE
OSTEOARTHRITIS JOINT
DISEASE

Dose per administration 650

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 (1)

Data signed: (b) (4) 26 Apr 2021 14:11:38

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	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2008	
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 (2)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication PARAXOTINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 (2)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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 2013	
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	☒

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication TRIAMTERENE/HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37.5/25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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	☒

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP SURGICAL PAIN
SECONDARY TO
OSTEOARTHRITIS

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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)		11 SEP 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)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication LEVONOX

Prophylaxis Yes ☒
No ☐

Indication POST OPERATIVE ANTI
COAGULANT

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 (5)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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)	09 SEP 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 (6)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication ELIQUIS

Prophylaxis Yes ☒
No ☐

Indication RIGHT ARTHROPLASTY
SECONDARY TO RIGHT HIP
OSTEOARTHRITIS

Dose per administration 2.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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)		12 SEP 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 (7)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA PROPHYLAXIS

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 10 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP ARTHROPLASTY
PAIN SECONDARY TO RIGHT
HIP OSTEOARTHRITIS

Dose per administration 5/325

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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)	12 SEP 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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS RT HIP

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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 SEP 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	☒

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication AZO

Prophylaxis Yes ☒
No ☐

Indication URINARY TRACT PAIN

Dose per administration 195

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) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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 SEP 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 (11)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA PAIN

Dose per administration 300

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
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 (13)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒
No ☐

Indication SHINGLES

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 (13)

Data signed: (b) (4) 26 Apr 2021 14:11:38

Generated On: 09 Jun 2021 16:08:31

	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)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 14:52:27

Generated On: 09 Jun 2021 16:08:31

[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

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
9 SEP 2020	HIP REPLACEMENT - RIGHT HIP	Medical History	
09 SEP 2020	PREOPERATIVE BLOODWORK	Adverse Event	
09 SEP 2020	XRAY- PELVIS	Adverse Event	
03 SEP 2020	PREOP - CHEST X-RAY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:08:31

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:08:31

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

SAEID	USA-US104-2020-MRNA-1273-P301000002
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

SAEID	USA-US104-2020-MRNA-1273-P301000002
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/SEP/2020 21:35
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

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

SAEID	USA-US104-2020-MRNA-1273-P301000002
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/NOV/2020 01:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

SAEID	USA-US104-2020-MRNA-1273-P301000002
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/NOV/2020 07:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

SAEID	USA-US104-2020-MRNA-1273-P301000002
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/DEC/2020 11:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 14:11:39

Generated On: 09 Jun 2021 16:08:31

SAEID	USA-US104-2020-MRNA-1273-P301000002
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 08:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3222315 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222315

Form: Participant Creation

Generated On: 09 Jun 2021 16:08:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'US3222315'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:19:28

US3222315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:00

US3222315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:19:29

US3222315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:00

US3222315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'SCRN'	System	24 Aug 2020 21:01:00

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:19:30

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '72'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'YEARS'	System	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '72'	System	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Female (F)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:08:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:14:26

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Aug 2020'	System	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '2020'	System	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Amendment 2 (2)'	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:11

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:19:29

US3222315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:08:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '1'	System	24 Aug 2020 21:01:18

US3222315

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:08:31

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	24 Aug 2020 21:01:18

US3222315

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:08:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:15:05

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:53:05
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'CONFIRM NO CONMED POSSIBLY DIET CONTROLLED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:15:30
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 18:03:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:17:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 15:17:31
Data point term sent to Coder	System	25 Aug 2020 15:16:24
User entered 'Diabetes, Type II'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'un UNK 1980'	Amber Vasquez (b) (4)	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 1980'	System	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '1980'	System	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:15:27

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:17:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:17:31
Data point term sent to Coder	System	25 Aug 2020 15:16:24
User entered 'Postmenopausal'	Amber Vasquez (b) (4)	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'un UNK 2005'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 2005'	System	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '2005'	System	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:15:44

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
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)	25 Aug 2020 15:17:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:17:30
Data point term sent to Coder	System	25 Aug 2020 15:16:25
User entered 'Allergies, Seasonal'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'un UNK 1980'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 1980'	System	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '1980'	System	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:16:15

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:38:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:38:38
Data point term sent to Coder	System	25 Aug 2020 15:17:27
User entered 'Allergies, Morphine'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'un UNK 1980'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 1980'	System	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '1980'	System	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:16:42

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:42:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:42:40
Data point term sent to Coder	System	25 Aug 2020 15:17:26
User entered 'Allergy, Codeine'	Amber Vasquez (b) (4)	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'un UNK 1980'	Amber Vasquez (b) (4)	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 1980'	System	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '1980'	System	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:17:08

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 14:11:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 14:11:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:44:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:44:45
Data point term sent to Coder	System	25 Aug 2020 15:18:28
User entered 'Allergy, Hydrocodone'	Amber Vasquez (b) (4)	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'un UNK 1980'	Amber Vasquez (b) (4)	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Amber Vasquez (b) (4)	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 1980'	System	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '1980'	System	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	25 Aug 2020 15:17:39

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:18:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:18:28
Data point term sent to Coder	System	10 Oct 2020 18:18:06
User entered 'ALLERGY TO DICLOFENAC'	Alicia Cevera (b) (4)	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:17:09

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:21:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:21:30
Data point term sent to Coder	System	10 Oct 2020 18:21:07
User entered 'HYSTERECTOMY'	Alicia Cevera (b) (4)	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'UN UNK 2005'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'UN UNK 2005'	Alicia Cevera (b) (4)	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Alicia Cevera (b) (4)	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 2005'	System	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '2005'	System	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 2005'	System	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '2005'	System	10 Oct 2020 18:21:05

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	10 Oct 2020 18:23:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 18:23:30
Data point term sent to Coder	System	10 Oct 2020 18:22:07
User entered 'BILATERAL CATARACTS'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:21:40

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Intraocular lens implant, LLT: Intraocular lens implant - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 05:21:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 05:21:19
Data point term sent to Coder	System	10 Oct 2020 18:25:10
User entered 'INTRAOCULAR LENS IMPLANTS-BILATERAL'	Alicia Cevera (b) (4)	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:25:02

US3222315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:33:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:33:22
Data point term sent to Coder	System	10 Oct 2020 18:32:13
User entered 'CHOLECYSTECTOMY'	Alicia Cevera (b) (4)	10 Oct 2020 18:31:19

US3222315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:31:19

US3222315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:31:19

US3222315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Oct 2020 18:36:31
User entered 'No (N)' reason for change: Data Entry Error	System	10 Oct 2020 18:36:31
User opened query 'Data is required. Please complete.' (Site from System).	Alicia Cevera (b) (4)	10 Oct 2020 18:36:31
User entered empty.	(b) (4)	
	System	10 Oct 2020 18:31:19
	Alicia Cevera (b) (4)	10 Oct 2020 18:31:19
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:31:19

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:31:19

US3222315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:31:19

US3222315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:31:19

US3222315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:31:19

US3222315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:31:19

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:33:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:33:21
Data point term sent to Coder	System	10 Oct 2020 18:32:13
User entered 'CHOLECYSTITIS'	Alicia Cevera (b) (4)	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 00:25:57
User entered 'No (N)' reason for change: Data Entry Error	System	11 Nov 2020 00:25:57
User opened query 'Data is required. Please complete.' (Site from System).	Albert Garcia (b) (4)	11 Nov 2020 00:25:57
User entered empty.	(b) (4)	
	System	10 Oct 2020 18:31:54
	Alicia Cevera (b) (4)	10 Oct 2020 18:31:54
	(b) (4)	

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:31:54

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:34:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:34:22
Data point term sent to Coder	System	10 Oct 2020 18:33:13
User entered 'BILATERAL CARPAL TUNNEL SYNDROME'	Alicia Cevera (b) (4)	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Oct 2020 18:34:03
User entered 'No (N)' reason for change: Data Entry Error	System	10 Oct 2020 18:34:03
User opened query 'Data is required. Please complete.' (Site from System).	Alicia Cevera (b) (4)	10 Oct 2020 18:34:03
User entered empty.	(b) (4)	
	System	10 Oct 2020 18:32:59
	Alicia Cevera (b) (4)	10 Oct 2020 18:32:59
	(b) (4)	

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:32:59

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:36:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:36:23
Data point term sent to Coder	System	10 Oct 2020 18:35:14
User entered 'BILATERAL CARPAL TUNNEL RELEASE'	Alicia Cevera (b) (4)	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:34:31

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder arthroplasty, LLT: Shoulder replacement - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 05:15:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 05:15:17
Data point term sent to Coder	System	10 Oct 2020 18:35:16
User entered 'LEFT SHOULDER REPLACED'	Alicia Cevera (b) (4)	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:35:04

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Shoulder osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:37:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:37:24
Data point term sent to Coder	System	10 Oct 2020 18:36:16
User entered 'OSTEOARTHRITIS LEFT SHOULDER'	Alicia Cevera (b) (4)	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	10 Oct 2020 18:37:03
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	10 Oct 2020 18:35:50
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 18:37:03
User entered '0'	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 18:35:50
	(b) (4)	

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Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:35:50

US3222315

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 19:06:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 19:06:21
Data point term sent to Coder	System	10 Oct 2020 19:05:29
User entered 'HYPERTENSION'	Alicia Cevera (b) (4)	10 Oct 2020 19:05:24
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
DataPoint inactivated with code reason code Data not required.	Alicia Cevera (b) (4)	10 Oct 2020 19:00:45

US3222315

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'UN UNK 2014'	Alicia Cevera (b) (4)	10 Oct 2020 19:05:24
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
DataPoint inactivated with code reason code Data not required.	Alicia Cevera (b) (4)	10 Oct 2020 19:00:45

US3222315

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 19:05:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Alicia Cevera (b) (4)	10 Oct 2020 19:00:45
	(b) (4)	

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 19:05:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Alicia Cevera (b) (4)	10 Oct 2020 19:00:45
	(b) (4)	

US3222315

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 19:05:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Alicia Cevera (b) (4)	10 Oct 2020 19:00:45
	(b) (4)	

US3222315

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 19:05:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Alicia Cevera (b) (4)	10 Oct 2020 19:00:45
	(b) (4)	

US3222315

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 2014'	System	10 Oct 2020 19:05:24
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 19:00:45
	(b) (4)	

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '2014'	System	10 Oct 2020 19:05:24
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
DataPoint inactivated with code reason code Data not required.	Alicia Cevera (b) (4)	10 Oct 2020 19:00:45

US3222315

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 19:05:24
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	10 Oct 2020 19:00:45

US3222315

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 19:05:24
DataPoint activated with code reason code Data required.	Alicia Cevera (b) (4)	10 Oct 2020 19:03:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	10 Oct 2020 19:00:45

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 12:09:43
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:59:52
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: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 18:41:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 18:41:26
Data point term sent to Coder	System	10 Oct 2020 18:40:19
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:40:08

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:43:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:43:26
Data point term sent to Coder	System	10 Oct 2020 18:42:20
User entered 'HYPERCHOLESTEROLEMIA'	Alicia Cevera (b) (4)	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:42:05

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Renal calculi - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:44:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:44:27
Data point term sent to Coder	System	10 Oct 2020 18:43:20
User entered 'RENAL CALCULI'	Alicia Cevera (b) (4)	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:42:24

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:45:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 18:45:28
Data point term sent to Coder	System	10 Oct 2020 18:44:21
User entered 'FIBROMYALGIA'	Alicia Cevera (b) (4)	10 Oct 2020 18:43:29

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	10 Oct 2020 18:49:18
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	10 Oct 2020 18:43:29
User entered empty.	Alicia Cevera (b) (4)	10 Oct 2020 18:43:29
	(b) (4)	

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 18:49:18
User entered '0'	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 18:43:29
	(b) (4)	

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Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:43:29

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 18:43:29

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:43:29

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:43:29

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:43:29

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:43:29

US3222315

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:43:29

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:57:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 18:57:20
Data point term sent to Coder	System	10 Oct 2020 18:56:24
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Alicia Cevera (b) (4)	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	10 Oct 2020 18:59:29
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	10 Oct 2020 18:55:31
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 18:59:29
User entered '1'	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 18:55:31
	(b) (4)	

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Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	10 Oct 2020 18:55:31

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 01:21:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 01:21:48
Data point term sent to Coder	System	11 Nov 2020 01:21:38
User entered 'OSTEOARTHRITIS - RIGHT HIP'	Albert Garcia (b) (4)	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:42:58
User entered 'un UNK 1998' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:42:58
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:42:58
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:42:58
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:42:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:42:58
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:42:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:42:58
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '9 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Albert Garcia (b) (4)	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 1998'	System	17 Mar 2021 16:42:58
User entered empty.	System	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '1998'	System	17 Mar 2021 16:42:58
User entered empty.	System	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	17 Mar 2021 16:42:58
User entered 'Sep 2020'	System	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	17 Mar 2021 16:42:58
User entered '2020'	System	11 Nov 2020 01:20:45

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 14:27:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 14:27:08
Data point term sent to Coder	System	02 Dec 2020 14:26:29
User entered 'depression'	gail lavine (b) (4)	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'un UNK 2013'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'Jan 2013'	System	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '2013'	System	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:08:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered empty.	System	02 Dec 2020 14:26:14

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	Amber Vasquez (b) (4)	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '16:05'	Amber Vasquez (b) (4)	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered '24 Aug 2020 16:05'	System	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '170.0' cm	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:18:49
DataPoint set to visible.	(b) (4) System	24 Aug 2020 21:01:18

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '81.6' kg	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:18:49
DataPoint set to visible.	(b) (4) System	24 Aug 2020 21:01:18

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
Amendment Manager: User entered '28.23529'	System	17 Sep 2020 00:21:58
User entered '28.2'	System	25 Aug 2020 15:18:49
DataPoint set to visible.	System	24 Aug 2020 21:01:18

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'kg/m2'	System	25 Aug 2020 15:18:49
DataPoint set to visible.	System	24 Aug 2020 21:01:18

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 20:14:31
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:49:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:49:47
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:22:37
User entered '36.5' C	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:47
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	25 Aug 2020 15:18:49
	(b) (4)	

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:47
User entered '61'	Albert Garcia (b) (4)	25 Aug 2020 15:18:49
	(b) (4)	

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'bpm'	System	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:47
User entered '16'	Albert Garcia (b) (4)	25 Aug 2020 15:18:49
	(b) (4)	

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'breaths/min'	System	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:47
User entered '130'	Albert Garcia (b) (4)	25 Aug 2020 15:18:49
	(b) (4)	

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'mmHg'	System	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:47
User entered '74'	Albert Garcia (b) (4)	25 Aug 2020 15:18:49
	(b) (4)	

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User entered 'mmHg'	System	25 Aug 2020 15:18:49

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53

US3222315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53

US3222315

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:19:01

US3222315

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:19:01

US3222315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:19:26

US3222315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:31

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:19:26

US3222315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:31

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:19:26

US3222315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:31

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:19:26

US3222315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:31

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:19:26

US3222315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:19:26

US3222315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:31

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'un UNK 2005'	Amber Vasquez (b) (4)	25 Aug 2020 15:19:26

US3222315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:08:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:19:26

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

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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)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

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Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:20:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 19:39:41
User entered 'No (N)' reason for change: Data Entry Error	System	06 Oct 2020 19:39:41
User opened query 'Data is required. Please complete.' (Site from System).	Albert Garcia (b) (4)	06 Oct 2020 19:39:41
User entered empty.	(b) (4)	
	System	25 Aug 2020 15:20:02
	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'retired'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:20:02

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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)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '1'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:08:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:14:53
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:20:02

US3222315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:20:27

US3222315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:20:27

US3222315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Clinic (Clinic)'	Amber Vasquez (b) (4)	25 Aug 2020 15:20:27

US3222315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'VISIT1'	System	25 Aug 2020 15:20:27

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:39:29

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '188030'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:39:29

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:39:29

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

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)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:59:06
Query ' PER CDM: Please complete this section of the form' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:50:29
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:50:24
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 19:39:31

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

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)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:50:24

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:50:24

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Albert Garcia (b) (4)	20 Sep 2020 21:50:24

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:50:24

US3222315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:08:31

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:50:24
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:29
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:45:10

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:24
User entered '170.0' cm	Albert Garcia (b) (4)	25 Aug 2020 15:22:39
	(b) (4)	

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:24
User entered '81.6' kg	Albert Garcia (b) (4)	25 Aug 2020 15:22:39
	(b) (4)	

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:24
User entered '170.0' cm	Albert Garcia (b) (4)	25 Aug 2020 15:22:39
	(b) (4)	

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:24
User entered '81.6' kg	Albert Garcia (b) (4)	25 Aug 2020 15:22:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '16:10'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '24 Aug 2020 16:10'	System	25 Aug 2020 15:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '36.5' C	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '65'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'bpm'	System	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '18'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'breaths/min'	System	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '134'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'mmHg'	System	25 Aug 2020 15:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '80'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'mmHg'	System	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:24
User entered '170.0' cm	Albert Garcia (b) (4)	25 Aug 2020 15:22:39
	(b) (4)	

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:49:24
User entered '81.6' kg	Albert Garcia (b) (4)	25 Aug 2020 15:22:39
	(b) (4)	

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '17:33'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '24 Aug 2020 17:33'	System	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '36.5' C	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '50'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'bpm'	System	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '16'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'breaths/min'	System	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '140'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'mmHg'	System	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '82'	Amber Vasquez (b) (4)	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'mmHg'	System	25 Aug 2020 15:22:39

US3222315

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:23:52

US3222315

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:23:52

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Jennifer Dittman (b) (4)	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

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)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Jennifer Dittman (b) (4)	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	Jennifer Dittman (b) (4)	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '16:58'	Jennifer Dittman (b) (4)	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '24 Aug 2020 16:58'	System	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Right Arm (RIGHT ARM)'	Jennifer Dittman (b) (4)	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'ONCE'	System	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 21:02:11

US3222315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:24:17

US3222315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	Amber Vasquez (b) (4)	25 Aug 2020 15:24:17

US3222315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '16:40'	Amber Vasquez (b) (4)	25 Aug 2020 15:24:17

US3222315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '24 Aug 2020 16:40'	System	25 Aug 2020 15:24:17

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:08:31

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '24 Aug 2020'	Amber Vasquez (b) (4)	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '16:41'	Amber Vasquez (b) (4)	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '24 Aug 2020 16:41'	System	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Amber Vasquez (b) (4)	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered empty.	System	25 Aug 2020 15:24:32

US3222315

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 15:24:40

US3222315

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	25 Aug 2020 15:24:40

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 17:18'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 19:48'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:17:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '08e54b2e-8ff7-4aeb-8219-35b5517fc08a' User entered 'Yes (Y)'	System	25 Aug 2020 10:18:09
	System	25 Aug 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:17:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '08e54b2e-8ff7-4aeb-8219-35b5517fc08a' User entered '98.6'	System	25 Aug 2020 10:18:09
	System	25 Aug 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:17:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '08e54b2e-8ff7-4aeb-8219-35b5517fc08a' User entered 'No (N)'	System	25 Aug 2020 10:18:09
	System	25 Aug 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:18:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '08e54b2e-8ff7-4aeb-8219-35b5517fc08a' User entered '25 Aug 2020 06:18'	System	25 Aug 2020 10:18:09
	System	25 Aug 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 20:43'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 2'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:12:16', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2cac72d0-933f-4e3a-9299-58d854cc4090' User entered 'Yes (Y)'	System	26 Aug 2020 10:12:47
	System	26 Aug 2020 10:12:47

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:12:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2cac72d0-933f-4e3a-9299-58d854cc4090' User entered '96.4'	System	26 Aug 2020 10:12:47
	System	26 Aug 2020 10:12:47

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:12:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2cac72d0-933f-4e3a-9299-58d854cc4090' User entered 'No (N)'	System	26 Aug 2020 10:12:47
	System	26 Aug 2020 10:12:47

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:12:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2cac72d0-933f-4e3a-9299-58d854cc4090' User entered '26 Aug 2020 06:12'	System	26 Aug 2020 10:12:47
	System	26 Aug 2020 10:12:47

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 3'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:23:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e05a3983-654a-45e1-8ee1-60b81f0686fd' User entered 'Yes (Y)'	System	27 Aug 2020 12:24:42
	System	27 Aug 2020 12:24:42

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:24:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e05a3983-654a-45e1-8ee1-60b81f0686fd' User entered '96.5'	System	27 Aug 2020 12:24:42
	System	27 Aug 2020 12:24:42

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:24:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e05a3983-654a-45e1-8ee1-60b81f0686fd' User entered 'No (N)'	System	27 Aug 2020 12:24:42
	System	27 Aug 2020 12:24:42

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:24:40', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e05a3983-654a-45e1-8ee1-60b81f0686fd' User entered '27 Aug 2020 08:24'	System	27 Aug 2020 12:24:42
	System	27 Aug 2020 12:24:42

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 4'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:40:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a412f54d-19fe-46fe-acbb-c8cc814bc03a' User entered 'No (N)'	System	28 Aug 2020 10:40:35
	System	28 Aug 2020 10:40:35

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:40:26', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a412f54d-19fe-46fe-acbb-c8cc814bc03a'	System	28 Aug 2020 10:40:35
User entered 'No (N)'	System	28 Aug 2020 10:40:35

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:40:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a412f54d-19fe-46fe-acbb-c8cc814bc03a' User entered '28 Aug 2020 06:40'	System	28 Aug 2020 10:40:35
	System	28 Aug 2020 10:40:35

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 5'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:07:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8ebc90a0-a78d-47c5-a2cb-a287e71b69db' User entered 'Yes (Y)'	System	29 Aug 2020 15:08:10
	System	29 Aug 2020 15:08:10

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:07:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8ebc90a0-a78d-47c5-a2cb-a287e71b69db' User entered '97.6'	System	29 Aug 2020 15:08:10
	System	29 Aug 2020 15:08:10

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8ebc90a0-a78d-47c5-a2cb-a287e71b69db' User entered 'No (N)'	System	29 Aug 2020 15:08:10
	System	29 Aug 2020 15:08:10

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8ebc90a0-a78d-47c5-a2cb-a287e71b69db' User entered '29 Aug 2020 11:08'	System	29 Aug 2020 15:08:10
	System	29 Aug 2020 15:08:10

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 6'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:34:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b5134752-c11e-41b0-a2e6-c07fed2d04ac' User entered 'Yes (Y)'	System	30 Aug 2020 13:35:57
	System	30 Aug 2020 13:35:57

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:34:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b5134752-c11e-41b0-a2e6-c07fed2d04ac' User entered '98.5'	System	30 Aug 2020 13:35:57
	System	30 Aug 2020 13:35:57

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:34:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b5134752-c11e-41b0-a2e6-c07fed2d04ac' User entered 'No (N)'	System	30 Aug 2020 13:35:57
	System	30 Aug 2020 13:35:57

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:34:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b5134752-c11e-41b0-a2e6-c07fed2d04ac' User entered '30 Aug 2020 09:34'	System	30 Aug 2020 13:35:57
	System	30 Aug 2020 13:35:57

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 7'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:01:30', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9bcbd3d1-3ffd-4d36-86e3-ff5e0ec3e28f' User entered 'Yes (Y)'	System	31 Aug 2020 11:01:55
	System	31 Aug 2020 11:01:55

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:01:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9bcbd3d1-3ffd-4d36-86e3-ff5e0ec3e28f' User entered '98.6'	System	31 Aug 2020 11:01:55
	System	31 Aug 2020 11:01:55

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:01:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9bcbd3d1-3ffd-4d36-86e3-ff5e0ec3e28f' User entered 'No (N)'	System	31 Aug 2020 11:01:55
	System	31 Aug 2020 11:01:55

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:01:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9bcbd3d1-3ffd-4d36-86e3-ff5e0ec3e28f' User entered '31 Aug 2020 07:01'	System	31 Aug 2020 11:01:55
	System	31 Aug 2020 11:01:55

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Please record - REDNESS AT INJECTION SITE (in mm)

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 17:18'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 19:48'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:18:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9b4179de-b1ee-4f85-9555-4273e0e2b1f1' User entered 'None (1)'	System	25 Aug 2020 10:18:56
	System	25 Aug 2020 10:18:56

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:18:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9b4179de-b1ee-4f85-9555-4273e0e2b1f1' User entered 'No (N)'	System	25 Aug 2020 10:18:56
	System	25 Aug 2020 10:18:56

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:18:39', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9b4179de-b1ee-4f85-9555-4273e0e2b1f1' User entered 'No (N)'	System	25 Aug 2020 10:18:56
	System	25 Aug 2020 10:18:56

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:18:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9b4179de-b1ee-4f85-9555-4273e0e2b1f1' User entered 'None (1)'	System	25 Aug 2020 10:18:56
	System	25 Aug 2020 10:18:56

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-25T06:18:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9b4179de-b1ee-4f85-9555-4273e0e2b1f1' User entered '25 Aug 2020 06:18'	System	25 Aug 2020 10:18:56
	System	25 Aug 2020 10:18:56

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 20:43'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 2'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:12:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcdac4ae-7e8a-44bf-ac6c-463d1ba97c70'	System	26 Aug 2020 10:13:13
User entered 'None (1)'	System	26 Aug 2020 10:13:13

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:12:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcdac4ae-7e8a-44bf-ac6c-463d1ba97c70'	System	26 Aug 2020 10:13:13
User entered 'No (N)'	System	26 Aug 2020 10:13:13

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcdac4ae-7e8a-44bf-ac6c-463d1ba97c70'	System	26 Aug 2020 10:13:13
User entered 'No (N)'	System	26 Aug 2020 10:13:13

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:05', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcdac4ae-7e8a-44bf-ac6c-463d1ba97c70'	System	26 Aug 2020 10:13:13
User entered 'None (1)'	System	26 Aug 2020 10:13:13

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcdac4ae-7e8a-44bf-ac6c-463d1ba97c70' User entered '26 Aug 2020 06:13'	System	26 Aug 2020 10:13:13
	System	26 Aug 2020 10:13:13

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 3'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:24:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '674bc39a-d3d8-4329-9416-3b211801ea03'	System	27 Aug 2020 12:25:15
User entered 'None (1)'	System	27 Aug 2020 12:25:15

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:24:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '674bc39a-d3d8-4329-9416-3b211801ea03' User entered 'No (N)'	System	27 Aug 2020 12:25:15
	System	27 Aug 2020 12:25:15

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '674bc39a-d3d8-4329-9416-3b211801ea03' User entered 'No (N)'	System	27 Aug 2020 12:25:15
	System	27 Aug 2020 12:25:15

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '674bc39a-d3d8-4329-9416-3b211801ea03'	System	27 Aug 2020 12:25:15
User entered 'None (1)'	System	27 Aug 2020 12:25:15

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:13', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '674bc39a-d3d8-4329-9416-3b211801ea03' User entered '27 Aug 2020 08:25'	System	27 Aug 2020 12:25:15
	System	27 Aug 2020 12:25:15

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 4'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:40:59', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd071b123-8adb-4f5b-8450-699c7b07676d' User entered 'None (1)'	System	28 Aug 2020 10:41:20
	System	28 Aug 2020 10:41:20

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd071b123-8adb-4f5b-8450-699c7b07676d' User entered 'No (N)'	System	28 Aug 2020 10:41:20
	System	28 Aug 2020 10:41:20

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd071b123-8adb-4f5b-8450-699c7b07676d' User entered 'No (N)'	System	28 Aug 2020 10:41:20
	System	28 Aug 2020 10:41:20

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:11', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd071b123-8adb-4f5b-8450-699c7b07676d' User entered 'None (1)'	System	28 Aug 2020 10:41:20
	System	28 Aug 2020 10:41:20

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:16', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd071b123-8adb-4f5b-8450-699c7b07676d' User entered '28 Aug 2020 06:41'	System	28 Aug 2020 10:41:20
	System	28 Aug 2020 10:41:20

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 5'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fae1e72a-b307-4afe-b63f-7f2fd60f1b43'	System	29 Aug 2020 15:08:39
User entered 'None (1)'	System	29 Aug 2020 15:08:39

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:21', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fae1e72a-b307-4afe-b63f-7f2fd60f1b43'	System	29 Aug 2020 15:08:39
User entered 'No (N)'	System	29 Aug 2020 15:08:39

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:25', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fae1e72a-b307-4afe-b63f-7f2fd60f1b43'	System	29 Aug 2020 15:08:39
User entered 'No (N)'	System	29 Aug 2020 15:08:39

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:32', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fae1e72a-b307-4afe-b63f-7f2fd60f1b43'	System	29 Aug 2020 15:08:39
User entered 'None (1)'	System	29 Aug 2020 15:08:39

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:36', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fae1e72a-b307-4afe-b63f-7f2fd60f1b43'	System	29 Aug 2020 15:08:39
User entered '29 Aug 2020 11:08'	System	29 Aug 2020 15:08:39

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 6'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:34:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6fa8d7f4-e2e6-420a-b300-0b0934901170' User entered 'None (1)'	System	30 Aug 2020 13:36:38
	System	30 Aug 2020 13:36:38

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:35:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6fa8d7f4-e2e6-420a-b300-0b0934901170' User entered 'No (N)'	System	30 Aug 2020 13:36:38
	System	30 Aug 2020 13:36:38

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:01', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6fa8d7f4-e2e6-420a-b300-0b0934901170' User entered 'No (N)'	System	30 Aug 2020 13:36:38
	System	30 Aug 2020 13:36:38

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:05', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6fa8d7f4-e2e6-420a-b300-0b0934901170' User entered 'None (1)'	System	30 Aug 2020 13:36:38
	System	30 Aug 2020 13:36:38

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6fa8d7f4-e2e6-420a-b300-0b0934901170' User entered '30 Aug 2020 09:36'	System	30 Aug 2020 13:36:38
	System	30 Aug 2020 13:36:38

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 7'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:01', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7927d1f2-45fb-4e7c-a154-10e49d54b7aa'	System	31 Aug 2020 11:02:26
User entered 'None (1)'	System	31 Aug 2020 11:02:26

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7927d1f2-45fb-4e7c-a154-10e49d54b7aa' User entered 'No (N)'	System	31 Aug 2020 11:02:26
	System	31 Aug 2020 11:02:26

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:13', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7927d1f2-45fb-4e7c-a154-10e49d54b7aa' User entered 'No (N)'	System	31 Aug 2020 11:02:26
	System	31 Aug 2020 11:02:26

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:18', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7927d1f2-45fb-4e7c-a154-10e49d54b7aa'	System	31 Aug 2020 11:02:26
User entered 'None (1)'	System	31 Aug 2020 11:02:26

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:24', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7927d1f2-45fb-4e7c-a154-10e49d54b7aa' User entered '31 Aug 2020 07:02'	System	31 Aug 2020 11:02:26
	System	31 Aug 2020 11:02:26

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 17:18'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 19:48'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Aug 2020 20:43'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 2'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49c2fb37-57ab-4e4d-934c-349d0c692acf' User entered 'None (0)'	System	26 Aug 2020 10:14:00
	System	26 Aug 2020 10:14:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49c2fb37-57ab-4e4d-934c-349d0c692acf' User entered 'No interference with activity (1)'	System	26 Aug 2020 10:14:00
	System	26 Aug 2020 10:14:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49c2fb37-57ab-4e4d-934c-349d0c692acf' User entered 'No interference with activity (1)'	System	26 Aug 2020 10:14:00
	System	26 Aug 2020 10:14:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49c2fb37-57ab-4e4d-934c-349d0c692acf' User entered 'No interference with activity (1)'	System	26 Aug 2020 10:14:00
	System	26 Aug 2020 10:14:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49c2fb37-57ab-4e4d-934c-349d0c692acf' User entered 'None (0)'	System	26 Aug 2020 10:14:00
	System	26 Aug 2020 10:14:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49c2fb37-57ab-4e4d-934c-349d0c692acf' User entered 'None (0)'	System	26 Aug 2020 10:14:00
	System	26 Aug 2020 10:14:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49c2fb37-57ab-4e4d-934c-349d0c692acf' User entered 'No (N)'	System	26 Aug 2020 10:14:00
	System	26 Aug 2020 10:14:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-26T06:13:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49c2fb37-57ab-4e4d-934c-349d0c692acf' User entered '26 Aug 2020 06:13'	System	26 Aug 2020 10:14:00
	System	26 Aug 2020 10:14:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 3'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '06d4451d-21d6-45ba-91ad-e122a73ef0f6' User entered 'None (0)'	System	27 Aug 2020 12:26:00
	System	27 Aug 2020 12:26:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '06d4451d-21d6-45ba-91ad-e122a73ef0f6' User entered 'None (0)'	System	27 Aug 2020 12:26:00
	System	27 Aug 2020 12:26:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:31', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '06d4451d-21d6-45ba-91ad-e122a73ef0f6' User entered 'None (0)'	System	27 Aug 2020 12:26:00
	System	27 Aug 2020 12:26:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '06d4451d-21d6-45ba-91ad-e122a73ef0f6' User entered 'None (0)'	System	27 Aug 2020 12:26:00
	System	27 Aug 2020 12:26:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '06d4451d-21d6-45ba-91ad-e122a73ef0f6' User entered 'None (0)'	System	27 Aug 2020 12:26:00
	System	27 Aug 2020 12:26:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '06d4451d-21d6-45ba-91ad-e122a73ef0f6' User entered 'None (0)'	System	27 Aug 2020 12:26:00
	System	27 Aug 2020 12:26:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '06d4451d-21d6-45ba-91ad-e122a73ef0f6'	System	27 Aug 2020 12:26:00
User entered 'No (N)'	System	27 Aug 2020 12:26:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-27T08:25:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '06d4451d-21d6-45ba-91ad-e122a73ef0f6' User entered '27 Aug 2020 08:25'	System	27 Aug 2020 12:26:00
	System	27 Aug 2020 12:26:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 4'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:23', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0cbe3560-781e-4d6f-a11e-220f8cd7ce5c' User entered 'None (0)'	System	28 Aug 2020 10:42:00
	System	28 Aug 2020 10:42:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0cbe3560-781e-4d6f-a11e-220f8cd7ce5c'	System	28 Aug 2020 10:42:00
User entered 'No interference with activity (1)'	System	28 Aug 2020 10:42:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0cbe3560-781e-4d6f-a11e-220f8cd7ce5c' User entered 'No interference with activity (1)'	System	28 Aug 2020 10:42:00
	System	28 Aug 2020 10:42:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:42', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0cbe3560-781e-4d6f-a11e-220f8cd7ce5c' User entered 'No interference with activity (1)'	System	28 Aug 2020 10:42:00
	System	28 Aug 2020 10:42:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0cbe3560-781e-4d6f-a11e-220f8cd7ce5c' User entered 'None (0)'	System	28 Aug 2020 10:42:00
	System	28 Aug 2020 10:42:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0cbe3560-781e-4d6f-a11e-220f8cd7ce5c' User entered 'None (0)'	System	28 Aug 2020 10:42:00
	System	28 Aug 2020 10:42:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0cbe3560-781e-4d6f-a11e-220f8cd7ce5c' User entered 'No (N)'	System	28 Aug 2020 10:42:00
	System	28 Aug 2020 10:42:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-28T06:41:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0cbe3560-781e-4d6f-a11e-220f8cd7ce5c' User entered '28 Aug 2020 06:41'	System	28 Aug 2020 10:42:00
	System	28 Aug 2020 10:42:00

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 5'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'df654990-33d1-4837-bdf4-ea43b21b6300' User entered 'None (0)'	System	29 Aug 2020 15:09:18
	System	29 Aug 2020 15:09:18

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'df654990-33d1-4837-bdf4-ea43b21b6300'	System	29 Aug 2020 15:09:18
User entered 'No interference with activity (1)'	System	29 Aug 2020 15:09:18

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'df654990-33d1-4837-bdf4-ea43b21b6300'	System	29 Aug 2020 15:09:18
User entered 'No interference with activity (1)'	System	29 Aug 2020 15:09:18

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:08:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'df654990-33d1-4837-bdf4-ea43b21b6300'	System	29 Aug 2020 15:09:18
User entered 'No interference with activity (1)'	System	29 Aug 2020 15:09:18

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:09:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'df654990-33d1-4837-bdf4-ea43b21b6300' User entered 'None (0)'	System	29 Aug 2020 15:09:18
	System	29 Aug 2020 15:09:18

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:09:05', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'df654990-33d1-4837-bdf4-ea43b21b6300' User entered 'None (0)'	System	29 Aug 2020 15:09:18
	System	29 Aug 2020 15:09:18

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:09:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'df654990-33d1-4837-bdf4-ea43b21b6300' User entered 'No (N)'	System	29 Aug 2020 15:09:18
	System	29 Aug 2020 15:09:18

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-29T11:09:13', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'df654990-33d1-4837-bdf4-ea43b21b6300' User entered '29 Aug 2020 11:09'	System	29 Aug 2020 15:09:18
	System	29 Aug 2020 15:09:18

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 6'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4a300150-23ed-4918-b16d-6e63af2ebd90' User entered 'None (0)'	System	30 Aug 2020 13:37:09
	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:21', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4a300150-23ed-4918-b16d-6e63af2ebd90'	System	30 Aug 2020 13:37:09
User entered 'No interference with activity (1)'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:25', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4a300150-23ed-4918-b16d-6e63af2ebd90'	System	30 Aug 2020 13:37:09
User entered 'No interference with activity (1)'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4a300150-23ed-4918-b16d-6e63af2ebd90'	System	30 Aug 2020 13:37:09
User entered 'No interference with activity (1)'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4a300150-23ed-4918-b16d-6e63af2ebd90' User entered 'None (0)'	System	30 Aug 2020 13:37:09
	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4a300150-23ed-4918-b16d-6e63af2ebd90' User entered 'None (0)'	System	30 Aug 2020 13:37:09
	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:42', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4a300150-23ed-4918-b16d-6e63af2ebd90' User entered 'No (N)'	System	30 Aug 2020 13:37:09
	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-30T09:36:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4a300150-23ed-4918-b16d-6e63af2ebd90' User entered '30 Aug 2020 09:36'	System	30 Aug 2020 13:37:09
	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 7'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:32', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da7ed7f9-b869-44f4-ad98-52207088c477'	System	31 Aug 2020 11:03:09
User entered 'No interference with activity (1)'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da7ed7f9-b869-44f4-ad98-52207088c477'	System	31 Aug 2020 11:03:09
User entered 'No interference with activity (1)'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da7ed7f9-b869-44f4-ad98-52207088c477'	System	31 Aug 2020 11:03:09
User entered 'No interference with activity (1)'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da7ed7f9-b869-44f4-ad98-52207088c477'	System	31 Aug 2020 11:03:09
User entered 'No interference with activity (1)'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da7ed7f9-b869-44f4-ad98-52207088c477' User entered 'None (0)'	System	31 Aug 2020 11:03:09
	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:02:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da7ed7f9-b869-44f4-ad98-52207088c477' User entered 'None (0)'	System	31 Aug 2020 11:03:09
	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:03:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da7ed7f9-b869-44f4-ad98-52207088c477'	System	31 Aug 2020 11:03:09
User entered 'No (N)'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-08-31T07:03:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da7ed7f9-b869-44f4-ad98-52207088c477'	System	31 Aug 2020 11:03:09
User entered '31 Aug 2020 07:03'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	31 Aug 2020 11:03:09
User entered 'Day 8'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:06:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '311ef90d-37ec-4109-8ff8-157b2ad46186' User entered 'None (0)'	System	01 Sep 2020 13:06:56
	System	01 Sep 2020 13:06:56

US3222315

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:06:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '311ef90d-37ec-4109-8ff8-157b2ad46186'	System	01 Sep 2020 13:06:56
User entered '01 Sep 2020 09:06'	System	01 Sep 2020 13:06:56

US3222315

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Aug 2020 12:00'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Aug 2020 13:37:09
User entered 'Day 8'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:06:16', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2b46a4b0-2a13-4705-b5e5-56048ecff422' User entered 'None (0)'	System	01 Sep 2020 13:06:42
	System	01 Sep 2020 13:06:42

US3222315

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:06:40', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2b46a4b0-2a13-4705-b5e5-56048ecff422' User entered '01 Sep 2020 09:06'	System	01 Sep 2020 13:06:42
	System	01 Sep 2020 13:06:42

US3222315

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Aug 2020 13:37:09
User entered 'Day 8'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:06:59', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0b900ac4-918a-4f66-8e10-823613a235d1'	System	01 Sep 2020 13:07:07
User entered 'No interference with activity (1)'	System	01 Sep 2020 13:07:07

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:07:04', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0b900ac4-918a-4f66-8e10-823613a235d1' User entered '01 Sep 2020 09:07'	System	01 Sep 2020 13:07:07
	System	01 Sep 2020 13:07:07

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	31 Aug 2020 11:03:09
User entered 'Day 9'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-02T07:27:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2e7af802-b2e8-4c44-a3fb-40cabfceab6d' User entered 'No interference with activity (1)'	System	02 Sep 2020 11:27:06
	System	02 Sep 2020 11:27:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-02T07:27:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2e7af802-b2e8-4c44-a3fb-40cabfceab6d' User entered '02 Sep 2020 07:27'	System	02 Sep 2020 11:27:06
	System	02 Sep 2020 11:27:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Sep 2020 13:07:07
User entered 'Day 10'	System	01 Sep 2020 13:07:07

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-03T06:18:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f13b6819-c4f8-46b1-a1f2-c1539093e9d6'	System	03 Sep 2020 10:18:09
User entered 'No interference with activity (1)'	System	03 Sep 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-03T06:18:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f13b6819-c4f8-46b1-a1f2-c1539093e9d6' User entered '03 Sep 2020 06:18'	System	03 Sep 2020 10:18:09
	System	03 Sep 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:07:07

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:07:07

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	02 Sep 2020 11:27:06
User entered 'Day 11'	System	02 Sep 2020 11:27:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-04T09:36:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0e06126e-ec75-4a96-bfa8-3b8413156b8e' User entered 'No interference with activity (1)'	System	04 Sep 2020 13:37:10
	System	04 Sep 2020 13:37:10

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-04T09:36:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0e06126e-ec75-4a96-bfa8-3b8413156b8e' User entered '04 Sep 2020 09:36'	System	04 Sep 2020 13:37:10
	System	04 Sep 2020 13:37:10

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 11:27:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 11:27:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Sep 2020 10:18:09
User entered 'Day 12'	System	03 Sep 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-05T07:37:24', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2d626008-cd1f-40a4-93d9-16df41469bac' User entered 'No interference with activity (1)'	System	05 Sep 2020 11:37:31
	System	05 Sep 2020 11:37:31

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-05T07:37:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2d626008-cd1f-40a4-93d9-16df41469bac' User entered '05 Sep 2020 07:37'	System	05 Sep 2020 11:37:31
	System	05 Sep 2020 11:37:31

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Sep 2020 13:37:10
User entered 'Day 13'	System	04 Sep 2020 13:37:10

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T09:15:21', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e699ce43-5d2d-47ef-aed6-98c411f69cf5'	System	06 Sep 2020 13:15:39
User entered 'No interference with activity (1)'	System	06 Sep 2020 13:15:39

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T09:15:26', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e699ce43-5d2d-47ef-aed6-98c411f69cf5' User entered '06 Sep 2020 09:15'	System	06 Sep 2020 13:15:39
	System	06 Sep 2020 13:15:39

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 13:37:10

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 13:37:10

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	05 Sep 2020 11:37:31
User entered 'Day 14'	System	05 Sep 2020 11:37:31

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T12:10:35', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5a1a1442-dd05-423c-84ab-ea2ccf80662e' User entered 'No interference with activity (1)'	System	06 Sep 2020 16:10:43
	System	06 Sep 2020 16:10:43

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T12:10:39', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5a1a1442-dd05-423c-84ab-ea2ccf80662e' User entered '06 Sep 2020 12:10'	System	06 Sep 2020 16:10:43
	System	06 Sep 2020 16:10:43

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 11:37:31

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 11:37:31

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	06 Sep 2020 13:15:39
User entered 'Day 15'	System	06 Sep 2020 13:15:39

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-07T12:33:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '3ff88bfb-7c67-4735-876c-4a30aba7d2dc'	System	07 Sep 2020 16:33:51
User entered 'No interference with activity (1)'	System	07 Sep 2020 16:33:51

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-07T12:33:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '3ff88bfb-7c67-4735-876c-4a30aba7d2dc' User entered '07 Sep 2020 12:33'	System	07 Sep 2020 16:33:51
	System	07 Sep 2020 16:33:51

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 13:15:39

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 13:15:39

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	06 Sep 2020 16:10:43
User entered 'Day 16'	System	06 Sep 2020 16:10:43

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-09T06:08:05', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '376d7583-874a-4b20-b4f7-fa35175e9df0'	System	09 Sep 2020 10:08:13
User entered 'No interference with activity (1)'	System	09 Sep 2020 10:08:13

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-09T06:08:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '376d7583-874a-4b20-b4f7-fa35175e9df0' User entered '09 Sep 2020 06:08'	System	09 Sep 2020 10:08:13
	System	09 Sep 2020 10:08:13

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 16:10:43

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 16:10:43

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Sep 2020 16:33:51
User entered 'Day 17'	System	07 Sep 2020 16:33:51

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:33:51

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:33:51

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	09 Sep 2020 10:08:13
User entered 'Day 18'	System	09 Sep 2020 10:08:13

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-10T14:08:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba13beac-d405-4f58-8102-5ede3eb67826' User entered 'No interference with activity (1)'	System	10 Sep 2020 18:09:06
	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-10T14:09:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba13beac-d405-4f58-8102-5ede3eb67826' User entered '10 Sep 2020 14:09'	System	10 Sep 2020 18:09:06
	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 10:08:13

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 10:08:13

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Sep 2020 18:09:06
User entered 'Day 19'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Sep 2020 18:09:06
User entered 'Day 20'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Aug 2020 13:37:09
User entered 'Day 8'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:07:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'c325cdfb-50a6-45a6-8b4a-c723ab28670a' User entered 'No interference with activity (1)'	System	01 Sep 2020 13:07:18
	System	01 Sep 2020 13:07:18

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:07:14', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'c325cdfb-50a6-45a6-8b4a-c723ab28670a' User entered '01 Sep 2020 09:07'	System	01 Sep 2020 13:07:18
	System	01 Sep 2020 13:07:18

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	31 Aug 2020 11:03:09
User entered 'Day 9'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-02T07:27:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e74fb1c2-641f-4ce8-8149-1384c4e81c39'	System	02 Sep 2020 11:27:14
User entered 'No interference with activity (1)'	System	02 Sep 2020 11:27:14

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-02T07:27:13', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e74fb1c2-641f-4ce8-8149-1384c4e81c39' User entered '02 Sep 2020 07:27'	System	02 Sep 2020 11:27:14
	System	02 Sep 2020 11:27:14

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Sep 2020 13:07:18
User entered 'Day 10'	System	01 Sep 2020 13:07:18

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-03T06:18:16', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd451fb7d-3c7e-46ad-baa4-c0bc9543032e' User entered 'No interference with activity (1)'	System	03 Sep 2020 10:18:24
	System	03 Sep 2020 10:18:24

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-03T06:18:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd451fb7d-3c7e-46ad-baa4-c0bc9543032e' User entered '03 Sep 2020 06:18'	System	03 Sep 2020 10:18:24
	System	03 Sep 2020 10:18:24

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:07:18

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:07:18

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	02 Sep 2020 11:27:14
User entered 'Day 11'	System	02 Sep 2020 11:27:14

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-04T09:37:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd7337721-3265-46a5-8cfa-16c8cb4b76a7'	System	04 Sep 2020 13:37:13
User entered 'No interference with activity (1)'	System	04 Sep 2020 13:37:13

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-04T09:37:05', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd7337721-3265-46a5-8cfa-16c8cb4b76a7' User entered '04 Sep 2020 09:37'	System	04 Sep 2020 13:37:13
	System	04 Sep 2020 13:37:13

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 11:27:14

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 11:27:14

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Sep 2020 10:18:24
User entered 'Day 12'	System	03 Sep 2020 10:18:24

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-05T07:37:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '99f722e4-6d3c-4ca8-b941-dd512ae62174'	System	05 Sep 2020 11:37:39
User entered 'No interference with activity (1)'	System	05 Sep 2020 11:37:39

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-05T07:37:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '99f722e4-6d3c-4ca8-b941-dd512ae62174' User entered '05 Sep 2020 07:37'	System	05 Sep 2020 11:37:39
	System	05 Sep 2020 11:37:39

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:18:24

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:18:24

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Sep 2020 13:37:13
User entered 'Day 13'	System	04 Sep 2020 13:37:13

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T09:15:32', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '80567482-c2ad-42b4-961f-037572d12b45'	System	06 Sep 2020 13:15:45
User entered 'No interference with activity (1)'	System	06 Sep 2020 13:15:45

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T09:15:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '80567482-c2ad-42b4-961f-037572d12b45' User entered '06 Sep 2020 09:15'	System	06 Sep 2020 13:15:45
	System	06 Sep 2020 13:15:45

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 13:37:13

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 13:37:13

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	05 Sep 2020 11:37:39
User entered 'Day 14'	System	05 Sep 2020 11:37:39

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T12:10:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76761943-1147-4a79-a110-0ac1f5eb4e3c'	System	06 Sep 2020 16:10:51
User entered 'No interference with activity (1)'	System	06 Sep 2020 16:10:51

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T12:10:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76761943-1147-4a79-a110-0ac1f5eb4e3c' User entered '06 Sep 2020 12:10'	System	06 Sep 2020 16:10:51
	System	06 Sep 2020 16:10:51

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 11:37:39

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 11:37:39

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	06 Sep 2020 13:15:45
User entered 'Day 15'	System	06 Sep 2020 13:15:45

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-07T12:33:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1f94f68e-9464-4a20-93ab-7fd1098c80f7'	System	07 Sep 2020 16:34:06
User entered 'No interference with activity (1)'	System	07 Sep 2020 16:34:06

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-07T12:34:01', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1f94f68e-9464-4a20-93ab-7fd1098c80f7'	System	07 Sep 2020 16:34:06
User entered '07 Sep 2020 12:34'	System	07 Sep 2020 16:34:06

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 13:15:45

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 13:15:45

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	06 Sep 2020 16:10:51
User entered 'Day 16'	System	06 Sep 2020 16:10:51

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-09T06:08:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1010556a-760b-4ffa-b83b-aef26ecdde88' User entered 'No interference with activity (1)'	System	09 Sep 2020 10:08:22
	System	09 Sep 2020 10:08:22

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-09T06:08:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1010556a-760b-4ffa-b83b-aef26ecdde88' User entered '09 Sep 2020 06:08'	System	09 Sep 2020 10:08:22
	System	09 Sep 2020 10:08:22

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 16:10:51

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 16:10:51

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Sep 2020 16:34:06
User entered 'Day 17'	System	07 Sep 2020 16:34:06

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:34:06

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:34:06

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	09 Sep 2020 10:08:22
User entered 'Day 18'	System	09 Sep 2020 10:08:22

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-10T14:09:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1c06e922-d7c8-44f4-ad8a-6aa0a65baa5f' User entered 'No interference with activity (1)'	System	10 Sep 2020 18:09:19
	System	10 Sep 2020 18:09:19

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-10T14:09:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1c06e922-d7c8-44f4-ad8a-6aa0a65baa5f' User entered '10 Sep 2020 14:09'	System	10 Sep 2020 18:09:19
	System	10 Sep 2020 18:09:19

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 10:08:22

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 10:08:22

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Sep 2020 18:09:19
User entered 'Day 19'	System	10 Sep 2020 18:09:19

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 18:09:19

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 18:09:19

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Sep 2020 18:09:19
User entered 'Day 20'	System	10 Sep 2020 18:09:19

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 18:09:19

US3222315

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 18:09:19

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Aug 2020 13:37:09
User entered 'Day 8'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:07:22', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a7e07902-a86d-4117-8ead-d719079c9f5a' User entered 'No (N)'	System	01 Sep 2020 13:07:30
	System	01 Sep 2020 13:07:30

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-01T09:07:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a7e07902-a86d-4117-8ead-d719079c9f5a' User entered '01 Sep 2020 09:07'	System	01 Sep 2020 13:07:30
	System	01 Sep 2020 13:07:30

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 13:37:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	31 Aug 2020 11:03:09
User entered 'Day 9'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-02T07:27:23', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a90572bf-0a98-4999-ac59-937b40df222e' User entered 'No (N)'	System	02 Sep 2020 11:27:28
	System	02 Sep 2020 11:27:28

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-02T07:27:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a90572bf-0a98-4999-ac59-937b40df222e' User entered '02 Sep 2020 07:27'	System	02 Sep 2020 11:27:28
	System	02 Sep 2020 11:27:28

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 11:03:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Sep 2020 13:07:07
User entered 'Day 10'	System	01 Sep 2020 13:07:07

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-03T06:18:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9bcd6d8a-66a9-4799-b9c3-74856cd76b9c' User entered 'No (N)'	System	03 Sep 2020 10:18:40
	System	03 Sep 2020 10:18:40

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-03T06:18:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9bcd6d8a-66a9-4799-b9c3-74856cd76b9c' User entered '03 Sep 2020 06:18'	System	03 Sep 2020 10:18:40
	System	03 Sep 2020 10:18:40

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:07:07

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:07:07

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	02 Sep 2020 11:27:06
User entered 'Day 11'	System	02 Sep 2020 11:27:06

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-04T09:37:14', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880024b2-138a-40ca-b588-4aed1cea0ee7' User entered 'No (N)'	System	04 Sep 2020 13:37:19
	System	04 Sep 2020 13:37:19

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-04T09:37:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880024b2-138a-40ca-b588-4aed1cea0ee7' User entered '04 Sep 2020 09:37'	System	04 Sep 2020 13:37:19
	System	04 Sep 2020 13:37:19

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 11:27:06

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 11:27:06

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Sep 2020 10:18:09
User entered 'Day 12'	System	03 Sep 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-05T07:37:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8d73c653-9ec9-40ba-94e6-6c664c870470' User entered 'No (N)'	System	05 Sep 2020 11:37:50
	System	05 Sep 2020 11:37:50

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-05T07:37:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8d73c653-9ec9-40ba-94e6-6c664c870470' User entered '05 Sep 2020 07:37'	System	05 Sep 2020 11:37:50
	System	05 Sep 2020 11:37:50

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:18:09

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Sep 2020 13:37:10
User entered 'Day 13'	System	04 Sep 2020 13:37:10

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T09:15:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '139c9fef-b469-43a9-b274-dae6e9781962' User entered 'No (N)'	System	06 Sep 2020 13:15:59
	System	06 Sep 2020 13:15:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T09:15:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '139c9fef-b469-43a9-b274-dae6e9781962'	System	06 Sep 2020 13:15:59
User entered '06 Sep 2020 09:15'	System	06 Sep 2020 13:15:59

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 13:37:10

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 13:37:10

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	05 Sep 2020 11:37:31
User entered 'Day 14'	System	05 Sep 2020 11:37:31

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T12:10:54', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0d7afc08-2dc3-47e3-8381-217ce2eaa7cf' User entered 'No (N)'	System	06 Sep 2020 16:11:03
	System	06 Sep 2020 16:11:03

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-06T12:10:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0d7afc08-2dc3-47e3-8381-217ce2eaa7cf' User entered '06 Sep 2020 12:10'	System	06 Sep 2020 16:11:03
	System	06 Sep 2020 16:11:03

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 11:37:31

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 11:37:31

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	06 Sep 2020 13:15:39
User entered 'Day 15'	System	06 Sep 2020 13:15:39

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-07T12:34:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '37ffac49-a191-4c24-944d-ee4feadfd9c' User entered 'No (N)'	System	07 Sep 2020 16:34:13
	System	07 Sep 2020 16:34:13

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-07T12:34:12', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '37ffac49-a191-4c24-944d-ee4feadfd9c' User entered '07 Sep 2020 12:34'	System	07 Sep 2020 16:34:13
	System	07 Sep 2020 16:34:13

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 13:15:39

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 13:15:39

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	06 Sep 2020 16:10:43
User entered 'Day 16'	System	06 Sep 2020 16:10:43

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-09T06:08:26', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da3e6c22-6fd8-42ff-a44a-090386475cd2'	System	09 Sep 2020 10:08:31
User entered 'No (N)'	System	09 Sep 2020 10:08:31

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-09T06:08:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'da3e6c22-6fd8-42ff-a44a-090386475cd2' User entered '09 Sep 2020 06:08'	System	09 Sep 2020 10:08:31
	System	09 Sep 2020 10:08:31

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 16:10:43

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 16:10:43

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Sep 2020 16:33:51
User entered 'Day 17'	System	07 Sep 2020 16:33:51

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:33:51

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:33:51

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	09 Sep 2020 10:08:13
User entered 'Day 18'	System	09 Sep 2020 10:08:13

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-10T14:09:24', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8b873fb4-e3ca-4d15-993d-dc5de86b18f8' User entered 'No (N)'	System	10 Sep 2020 18:09:29
	System	10 Sep 2020 18:09:29

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-10T14:09:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8b873fb4-e3ca-4d15-993d-dc5de86b18f8' User entered '10 Sep 2020 14:09'	System	10 Sep 2020 18:09:29
	System	10 Sep 2020 18:09:29

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 10:08:13

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 10:08:13

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Sep 2020 18:09:06
User entered 'Day 19'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Sep 2020 18:09:06
User entered 'Day 20'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 18:09:06

US3222315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 18:09:06

US3222315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:15:57

US3222315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '31 Aug 2020'	Alicia Cevera (b) (4)	22 Oct 2020 19:15:57

US3222315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Contact Made (CONTACT MADE)'	Alicia Cevera (b) (4)	22 Oct 2020 19:15:57

US3222315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 19:15:57

US3222315

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	22 Sep 2020 17:03:11
User entered 'No (N)'	Jennifer Dittman (b) (4)	22 Sep 2020 17:03:07

US3222315

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	22 Sep 2020 17:03:11
User entered empty.	System	22 Sep 2020 17:03:07

US3222315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	22 Oct 2020 19:16:28

US3222315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '07 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 16:25:19
User entered '7 Sep 2020'	Alicia Cevera (b) (4)	22 Oct 2020 19:16:28

US3222315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:46:45
User entered 'Contact Made (CONTACT MADE)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:16:28

US3222315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'THREE CALL ATTEMPTS WERE MADE: 7SEP, 8SEP, AND 9SEP WITH NO SUCCESS' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:46:45
User entered empty.	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:16:28

US3222315

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	22 Sep 2020 17:03:17

US3222315

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	22 Sep 2020 17:03:17

US3222315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	22 Oct 2020 19:18:12

US3222315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '14 Sep 2020'	Alicia Cevera (b) (4)	22 Oct 2020 19:18:12

US3222315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alicia Cevera (b) (4)	22 Oct 2020 19:18:12

US3222315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'CALLS ATTEMPTED WITH MESAGES LEFT AND NO RETURN CALLS ON SEP. 14,15,16 AND 19.'	(b) (4) Alicia Cevera (b) (4)	22 Oct 2020 19:18:12

US3222315

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	22 Sep 2020 17:03:23

US3222315

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	22 Sep 2020 17:03:23

US3222315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	22 Sep 2020 17:03:34

US3222315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '22 Sep 2020'	Jennifer Dittman (b) (4)	22 Sep 2020 17:03:34

US3222315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	22 Sep 2020 17:03:34

US3222315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'VISIT2'	System	22 Sep 2020 17:03:34

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User accepted default value 'Pre-Dose (PREDOSE)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '22 Sep 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '11:32'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '22 Sep 2020 11:32'	System	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '36.9' C	Alicia Cevera (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Oral (Oral)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '77'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'bpm'	System	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '16'	Alicia Cevera (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'breaths/min'	System	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '110'	Alicia Cevera (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'mmHg'	System	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '62'	Alicia Cevera (b) (4)	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'mmHg'	System	10 Oct 2020 19:57:55

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User accepted default value 'Post-Dose (POSTDOSE)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '22 Sep 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '13:04'	Alicia Cevera (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '22 Sep 2020 13:04'	System	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '36.9' C	Alicia Cevera (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Oral (Oral)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '68'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'bpm'	System	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '17'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'breaths/min'	System	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '120'	Alicia Cevera (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'mmHg'	System	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '82'	Alicia Cevera (b) (4)	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'mmHg'	System	10 Oct 2020 20:00:29

US3222315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:48

US3222315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:00:48

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Per CDM: V2D29 visit was performed, Please complete VITAL SIGNS, PHYSICAL EXAMINATION IMMUNOGENICITY ASSESSMENT, CENTRAL LABORATORY - NASOPHARYNGEAL SWAB Pages.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:58:04
Query 'Per CDM: V2D29 visit was performed, Please complete VITAL SIGNS, PHYSICAL EXAMINATION IMMUNOGENICITY ASSESSMENT, CENTRAL LABORATORY - NASOPHARYNGEAL SWAB Pages.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Oct 2020 11:51:38
User opened query 'Per CDM: V2D29 visit was performed, Please complete VITAL SIGNS, PHYSICAL EXAMINATION IMMUNOGENICITY ASSESSMENT, CENTRAL LABORATORY - NASOPHARYNGEAL SWAB Pages.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 10:27:36
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Jennifer Dittman (b) (4)	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

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)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Jennifer Dittman (b) (4)	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '22 Sep 2020'	Jennifer Dittman (b) (4)	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '12:34'	Jennifer Dittman (b) (4)	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '22 Sep 2020 12:34'	System	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	17 Oct 2020 11:51:45
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	17 Oct 2020 11:51:45
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Albert Garcia (b) (4)	17 Oct 2020 11:51:45
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	22 Sep 2020 17:04:08
User entered 'Left Arm (LEFT ARM)'	System	22 Sep 2020 17:04:08
	Jennifer Dittman (b) (4)	22 Sep 2020 17:04:08
	(b) (4)	

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'ONCE'	System	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 17:04:08

US3222315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 20:01:04

US3222315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '22 Sep 2020'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 20:01:04

US3222315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '11:45'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:01:04

US3222315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '22 Sep 2020 11:45'	System	10 Oct 2020 20:01:04

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:08:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query 'Per GCL Reconciliation: Swab sample collected on 22SEP2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Visit 2 Day 29". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 09:42:54
Query 'Per GCL Reconciliation: Swab sample collected on 22SEP2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Visit 2 Day 29". Please verify the correct visit for sample collected on this date.' answered with 'THIS QUERY WILL BE ADDRESSED BY THE LAB. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 00:35:22
User opened query 'Per GCL Reconciliation: Swab sample collected on 22SEP2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Visit 2 Day 29". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:16:04
User entered '22 Sep 2020'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:03:06

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:03:06

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:03:06

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	10 Oct 2020 20:03:56
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	10 Oct 2020 20:03:56
User entered '11:48' reason for change: Data Entry Error	Alicia Cevera (b) (4)	10 Oct 2020 20:03:56
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	10 Oct 2020 20:03:06
User entered empty.	System	10 Oct 2020 20:03:06
	Alicia Cevera (b) (4)	10 Oct 2020 20:03:06
	(b) (4)	

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '22 Sep 2020 11:48'	System	10 Oct 2020 20:03:56
User entered empty.	System	10 Oct 2020 20:03:06

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:03:06

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:03:06

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 20:03:06

US3222315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered empty.	System	10 Oct 2020 20:03:06

US3222315

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	22 Sep 2020 17:04:15

US3222315

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	22 Sep 2020 17:04:15

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ffc38ed0-c950-4bc9-9579-a8914008c0e5' User entered 'Yes (Y)'	System	22 Sep 2020 17:13:32
	System	22 Sep 2020 17:13:32

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ffc38ed0-c950-4bc9-9579-a8914008c0e5' User entered '98.4'	System	22 Sep 2020 17:13:32
	System	22 Sep 2020 17:13:32

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:22', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ffc38ed0-c950-4bc9-9579-a8914008c0e5' User entered 'No (N)'	System	22 Sep 2020 17:13:32
	System	22 Sep 2020 17:13:32

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ffc38ed0-c950-4bc9-9579-a8914008c0e5' User entered '22 Sep 2020 13:13'	System	22 Sep 2020 17:13:32
	System	22 Sep 2020 17:13:32

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 12:54'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 15:24'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:52:25', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f3943fdb-fd1b-492b-b04a-547e07b80de7' User entered 'Yes (Y)'	System	23 Sep 2020 11:52:55
	System	23 Sep 2020 11:52:55

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:52:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f3943fdb-fd1b-492b-b04a-547e07b80de7' User entered '97.3'	System	23 Sep 2020 11:52:55
	System	23 Sep 2020 11:52:55

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:52:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f3943fdb-fd1b-492b-b04a-547e07b80de7' User entered 'No (N)'	System	23 Sep 2020 11:52:55
	System	23 Sep 2020 11:52:55

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:52:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f3943fdb-fd1b-492b-b04a-547e07b80de7' User entered '23 Sep 2020 07:52'	System	23 Sep 2020 11:52:55
	System	23 Sep 2020 11:52:55

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 16:19'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 2'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:00:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '031a6625-2d7f-4231-a15e-b7b0a786be39' User entered 'Yes (Y)'	System	23 Sep 2020 18:01:09
	System	23 Sep 2020 18:01:09

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:00:54', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '031a6625-2d7f-4231-a15e-b7b0a786be39' User entered '98.3'	System	23 Sep 2020 18:01:09
	System	23 Sep 2020 18:01:09

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:00:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '031a6625-2d7f-4231-a15e-b7b0a786be39' User entered 'No (N)'	System	23 Sep 2020 18:01:09
	System	23 Sep 2020 18:01:09

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '031a6625-2d7f-4231-a15e-b7b0a786be39' User entered '23 Sep 2020 14:01'	System	23 Sep 2020 18:01:09
	System	23 Sep 2020 18:01:09

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 3'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 4'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:04', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4f021df0-dd53-4c87-83ae-104ecca1da7d' User entered 'Yes (Y)'	System	25 Sep 2020 16:02:09
	System	25 Sep 2020 16:02:09

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4f021df0-dd53-4c87-83ae-104ecca1da7d' User entered '97.3'	System	25 Sep 2020 16:02:09
	System	25 Sep 2020 16:02:09

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4f021df0-dd53-4c87-83ae-104ecca1da7d' User entered 'No (N)'	System	25 Sep 2020 16:02:09
	System	25 Sep 2020 16:02:09

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4f021df0-dd53-4c87-83ae-104ecca1da7d' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 16:02:09
	System	25 Sep 2020 16:02:09

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 5'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:10:36', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd211526d-37d8-4058-b874-d7442af4256f' User entered 'Yes (Y)'	System	26 Sep 2020 16:10:55
	System	26 Sep 2020 16:10:55

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:10:42', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd211526d-37d8-4058-b874-d7442af4256f' User entered '97.4'	System	26 Sep 2020 16:10:55
	System	26 Sep 2020 16:10:55

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:10:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd211526d-37d8-4058-b874-d7442af4256f' User entered 'No (N)'	System	26 Sep 2020 16:10:55
	System	26 Sep 2020 16:10:55

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:10:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd211526d-37d8-4058-b874-d7442af4256f' User entered '26 Sep 2020 12:10'	System	26 Sep 2020 16:10:55
	System	26 Sep 2020 16:10:55

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 6'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49e6ba11-43b5-4225-b781-df9356b1e4bd' User entered 'No (N)'	System	28 Sep 2020 11:40:30
	System	28 Sep 2020 11:40:30

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49e6ba11-43b5-4225-b781-df9356b1e4bd' User entered 'No (N)'	System	28 Sep 2020 11:40:30
	System	28 Sep 2020 11:40:30

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:25', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '49e6ba11-43b5-4225-b781-df9356b1e4bd' User entered '28 Sep 2020 07:40'	System	28 Sep 2020 11:40:30
	System	28 Sep 2020 11:40:30

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 7'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:00:50', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2dea986a-4b13-46ef-96a1-147ef105d663' User entered 'Yes (Y)'	System	29 Sep 2020 10:01:08
	System	29 Sep 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:00:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2dea986a-4b13-46ef-96a1-147ef105d663' User entered '97.3'	System	29 Sep 2020 10:01:08
	System	29 Sep 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2dea986a-4b13-46ef-96a1-147ef105d663' User entered 'No (N)'	System	29 Sep 2020 10:01:08
	System	29 Sep 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2dea986a-4b13-46ef-96a1-147ef105d663' User entered '29 Sep 2020 06:01'	System	29 Sep 2020 10:01:08
	System	29 Sep 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9316fd92-20d0-4ae0-b507-3023432e6f14' User entered 'None (1)'	System	22 Sep 2020 17:13:59
	System	22 Sep 2020 17:13:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9316fd92-20d0-4ae0-b507-3023432e6f14' User entered 'No (N)'	System	22 Sep 2020 17:13:59
	System	22 Sep 2020 17:13:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9316fd92-20d0-4ae0-b507-3023432e6f14' User entered 'No (N)'	System	22 Sep 2020 17:13:59
	System	22 Sep 2020 17:13:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9316fd92-20d0-4ae0-b507-3023432e6f14' User entered 'None (1)'	System	22 Sep 2020 17:13:59
	System	22 Sep 2020 17:13:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:13:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9316fd92-20d0-4ae0-b507-3023432e6f14' User entered '22 Sep 2020 13:13'	System	22 Sep 2020 17:13:59
	System	22 Sep 2020 17:13:59

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 12:54'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 15:24'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:11', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '89084f89-72a4-40ba-a472-86ab627bc342'	System	23 Sep 2020 11:53:35
User entered 'None (1)'	System	23 Sep 2020 11:53:35

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:16', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '89084f89-72a4-40ba-a472-86ab627bc342'	System	23 Sep 2020 11:53:35
User entered 'No (N)'	System	23 Sep 2020 11:53:35

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:21', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '89084f89-72a4-40ba-a472-86ab627bc342' User entered 'No (N)'	System	23 Sep 2020 11:53:35
	System	23 Sep 2020 11:53:35

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '89084f89-72a4-40ba-a472-86ab627bc342'	System	23 Sep 2020 11:53:35
User entered 'None (1)'	System	23 Sep 2020 11:53:35

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:30', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '89084f89-72a4-40ba-a472-86ab627bc342'	System	23 Sep 2020 11:53:35
User entered '23 Sep 2020 07:53'	System	23 Sep 2020 11:53:35

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 16:19'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 2'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:12', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7523471c-1746-4ecf-ab54-252d5067d4ed' User entered 'None (1)'	System	23 Sep 2020 18:01:50
	System	23 Sep 2020 18:01:50

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:16', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7523471c-1746-4ecf-ab54-252d5067d4ed' User entered 'No (N)'	System	23 Sep 2020 18:01:50
	System	23 Sep 2020 18:01:50

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7523471c-1746-4ecf-ab54-252d5067d4ed' User entered 'No (N)'	System	23 Sep 2020 18:01:50
	System	23 Sep 2020 18:01:50

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:24', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7523471c-1746-4ecf-ab54-252d5067d4ed' User entered 'None (1)'	System	23 Sep 2020 18:01:50
	System	23 Sep 2020 18:01:50

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7523471c-1746-4ecf-ab54-252d5067d4ed' User entered '23 Sep 2020 14:01'	System	23 Sep 2020 18:01:50
	System	23 Sep 2020 18:01:50

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 3'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 4'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba41f748-2b76-44c0-a021-0a947b65792a' User entered 'None (1)'	System	25 Sep 2020 16:02:53
	System	25 Sep 2020 16:02:53

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:30', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba41f748-2b76-44c0-a021-0a947b65792a' User entered 'No (N)'	System	25 Sep 2020 16:02:53
	System	25 Sep 2020 16:02:53

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba41f748-2b76-44c0-a021-0a947b65792a' User entered 'No (N)'	System	25 Sep 2020 16:02:53
	System	25 Sep 2020 16:02:53

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:39', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba41f748-2b76-44c0-a021-0a947b65792a' User entered 'None (1)'	System	25 Sep 2020 16:02:53
	System	25 Sep 2020 16:02:53

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba41f748-2b76-44c0-a021-0a947b65792a' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 16:02:53
	System	25 Sep 2020 16:02:53

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 5'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:01', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4187241d-0fb0-44f3-8c2c-8cd8468f8a8f' User entered 'None (1)'	System	26 Sep 2020 16:11:19
	System	26 Sep 2020 16:11:19

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:04', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4187241d-0fb0-44f3-8c2c-8cd8468f8a8f' User entered 'No (N)'	System	26 Sep 2020 16:11:19
	System	26 Sep 2020 16:11:19

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4187241d-0fb0-44f3-8c2c-8cd8468f8a8f' User entered 'No (N)'	System	26 Sep 2020 16:11:19
	System	26 Sep 2020 16:11:19

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:14', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4187241d-0fb0-44f3-8c2c-8cd8468f8a8f' User entered 'None (1)'	System	26 Sep 2020 16:11:19
	System	26 Sep 2020 16:11:19

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4187241d-0fb0-44f3-8c2c-8cd8468f8a8f' User entered '26 Sep 2020 12:11'	System	26 Sep 2020 16:11:19
	System	26 Sep 2020 16:11:19

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 6'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcee6228-bb9c-44df-9b5f-515ce4d84c3d'	System	28 Sep 2020 11:40:51
User entered 'None (1)'	System	28 Sep 2020 11:40:51

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcee6228-bb9c-44df-9b5f-515ce4d84c3d' User entered 'No (N)'	System	28 Sep 2020 11:40:51
	System	28 Sep 2020 11:40:51

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:40', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcee6228-bb9c-44df-9b5f-515ce4d84c3d' User entered 'No (N)'	System	28 Sep 2020 11:40:51
	System	28 Sep 2020 11:40:51

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcee6228-bb9c-44df-9b5f-515ce4d84c3d'	System	28 Sep 2020 11:40:51
User entered 'None (1)'	System	28 Sep 2020 11:40:51

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fcee6228-bb9c-44df-9b5f-515ce4d84c3d' User entered '28 Sep 2020 07:40'	System	28 Sep 2020 11:40:51
	System	28 Sep 2020 11:40:51

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 7'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:12', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '485d0eda-436b-493b-9812-2f478e356f37'	System	29 Sep 2020 10:01:30
User entered 'None (1)'	System	29 Sep 2020 10:01:30

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:16', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '485d0eda-436b-493b-9812-2f478e356f37' User entered 'No (N)'	System	29 Sep 2020 10:01:30
	System	29 Sep 2020 10:01:30

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:19', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '485d0eda-436b-493b-9812-2f478e356f37' User entered 'No (N)'	System	29 Sep 2020 10:01:30
	System	29 Sep 2020 10:01:30

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:24', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '485d0eda-436b-493b-9812-2f478e356f37'	System	29 Sep 2020 10:01:30
User entered 'None (1)'	System	29 Sep 2020 10:01:30

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '485d0eda-436b-493b-9812-2f478e356f37' User entered '29 Sep 2020 06:01'	System	29 Sep 2020 10:01:30
	System	29 Sep 2020 10:01:30

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:14:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fd9836d6-6c81-4a73-91e0-fe8470d91e29' User entered 'None (0)'	System	22 Sep 2020 17:14:33
	System	22 Sep 2020 17:14:33

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:14:07', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fd9836d6-6c81-4a73-91e0-fe8470d91e29' User entered 'None (0)'	System	22 Sep 2020 17:14:33
	System	22 Sep 2020 17:14:33

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:14:11', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fd9836d6-6c81-4a73-91e0-fe8470d91e29' User entered 'None (0)'	System	22 Sep 2020 17:14:33
	System	22 Sep 2020 17:14:33

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:14:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fd9836d6-6c81-4a73-91e0-fe8470d91e29' User entered 'None (0)'	System	22 Sep 2020 17:14:33
	System	22 Sep 2020 17:14:33

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:14:18', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fd9836d6-6c81-4a73-91e0-fe8470d91e29' User entered 'None (0)'	System	22 Sep 2020 17:14:33
	System	22 Sep 2020 17:14:33

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:14:21', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fd9836d6-6c81-4a73-91e0-fe8470d91e29' User entered 'None (0)'	System	22 Sep 2020 17:14:33
	System	22 Sep 2020 17:14:33

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:14:25', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fd9836d6-6c81-4a73-91e0-fe8470d91e29' User entered 'No (N)'	System	22 Sep 2020 17:14:33
	System	22 Sep 2020 17:14:33

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-22T13:14:28', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fd9836d6-6c81-4a73-91e0-fe8470d91e29' User entered '22 Sep 2020 13:14'	System	22 Sep 2020 17:14:33
	System	22 Sep 2020 17:14:33

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 12:54'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 15:24'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2bdf898-b79d-4edb-8a92-54a5cf1a572e' User entered 'None (0)'	System	23 Sep 2020 11:54:15
	System	23 Sep 2020 11:54:15

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2bdf898-b79d-4edb-8a92-54a5cf1a572e'	System	23 Sep 2020 11:54:15
User entered 'No interference with activity (1)'	System	23 Sep 2020 11:54:15

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2bdf898-b79d-4edb-8a92-54a5cf1a572e' User entered 'None (0)'	System	23 Sep 2020 11:54:15
	System	23 Sep 2020 11:54:15

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:53:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2bdf898-b79d-4edb-8a92-54a5cf1a572e'	System	23 Sep 2020 11:54:15
User entered 'No interference with activity (1)'	System	23 Sep 2020 11:54:15

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:54:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2bdf898-b79d-4edb-8a92-54a5cf1a572e' User entered 'None (0)'	System	23 Sep 2020 11:54:15
	System	23 Sep 2020 11:54:15

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:54:04', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2bdf898-b79d-4edb-8a92-54a5cf1a572e' User entered 'None (0)'	System	23 Sep 2020 11:54:15
	System	23 Sep 2020 11:54:15

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:54:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2bdf898-b79d-4edb-8a92-54a5cf1a572e' User entered 'No (N)'	System	23 Sep 2020 11:54:15
	System	23 Sep 2020 11:54:15

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T07:54:12', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2bdf898-b79d-4edb-8a92-54a5cf1a572e' User entered '23 Sep 2020 07:54'	System	23 Sep 2020 11:54:15
	System	23 Sep 2020 11:54:15

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Sep 2020 16:19'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 2'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76fec436-3cac-44c1-a0e4-21b1e791e53c'	System	23 Sep 2020 18:01:59
User entered 'No interference with activity (1)'	System	23 Sep 2020 18:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76fec436-3cac-44c1-a0e4-21b1e791e53c' User entered 'None (0)'	System	23 Sep 2020 18:01:59
	System	23 Sep 2020 18:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76fec436-3cac-44c1-a0e4-21b1e791e53c' User entered 'None (0)'	System	23 Sep 2020 18:01:59
	System	23 Sep 2020 18:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76fec436-3cac-44c1-a0e4-21b1e791e53c'	System	23 Sep 2020 18:01:59
User entered 'No interference with activity (1)'	System	23 Sep 2020 18:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76fec436-3cac-44c1-a0e4-21b1e791e53c' User entered 'None (0)'	System	23 Sep 2020 18:01:59
	System	23 Sep 2020 18:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76fec436-3cac-44c1-a0e4-21b1e791e53c' User entered 'None (0)'	System	23 Sep 2020 18:01:59
	System	23 Sep 2020 18:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:55', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76fec436-3cac-44c1-a0e4-21b1e791e53c' User entered 'No (N)'	System	23 Sep 2020 18:01:59
	System	23 Sep 2020 18:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-23T14:01:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '76fec436-3cac-44c1-a0e4-21b1e791e53c' User entered '23 Sep 2020 14:01'	System	23 Sep 2020 18:01:59
	System	23 Sep 2020 18:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 3'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 4'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:50', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1a4bba0-6723-45a8-be70-ac253f318b4c' User entered 'None (0)'	System	25 Sep 2020 16:03:41
	System	25 Sep 2020 16:03:41

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:55', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1a4bba0-6723-45a8-be70-ac253f318b4c' User entered 'None (0)'	System	25 Sep 2020 16:03:41
	System	25 Sep 2020 16:03:41

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:01:59', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1a4bba0-6723-45a8-be70-ac253f318b4c' User entered 'No interference with activity (1)'	System	25 Sep 2020 16:03:41
	System	25 Sep 2020 16:03:41

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:02:04', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1a4bba0-6723-45a8-be70-ac253f318b4c' User entered 'No interference with activity (1)'	System	25 Sep 2020 16:03:41
	System	25 Sep 2020 16:03:41

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:02:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1a4bba0-6723-45a8-be70-ac253f318b4c' User entered 'None (0)'	System	25 Sep 2020 16:03:41
	System	25 Sep 2020 16:03:41

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:02:11', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1a4bba0-6723-45a8-be70-ac253f318b4c' User entered 'None (0)'	System	25 Sep 2020 16:03:41
	System	25 Sep 2020 16:03:41

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:02:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1a4bba0-6723-45a8-be70-ac253f318b4c' User entered 'No (N)'	System	25 Sep 2020 16:03:41
	System	25 Sep 2020 16:03:41

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-25T12:02:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1a4bba0-6723-45a8-be70-ac253f318b4c' User entered '25 Sep 2020 12:02'	System	25 Sep 2020 16:03:41
	System	25 Sep 2020 16:03:41

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 5'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:23', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cf6b0cc9-aaa9-4b0e-a5b2-e92b31ab9550' User entered 'None (0)'	System	26 Sep 2020 16:11:50
	System	26 Sep 2020 16:11:50

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cf6b0cc9-aaa9-4b0e-a5b2-e92b31ab9550'	System	26 Sep 2020 16:11:50
User entered 'No interference with activity (1)'	System	26 Sep 2020 16:11:50

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:30', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cf6b0cc9-aaa9-4b0e-a5b2-e92b31ab9550'	System	26 Sep 2020 16:11:50
User entered 'No interference with activity (1)'	System	26 Sep 2020 16:11:50

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:35', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cf6b0cc9-aaa9-4b0e-a5b2-e92b31ab9550'	System	26 Sep 2020 16:11:50
User entered 'No interference with activity (1)'	System	26 Sep 2020 16:11:50

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cf6b0cc9-aaa9-4b0e-a5b2-e92b31ab9550' User entered 'None (0)'	System	26 Sep 2020 16:11:50
	System	26 Sep 2020 16:11:50

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cf6b0cc9-aaa9-4b0e-a5b2-e92b31ab9550' User entered 'None (0)'	System	26 Sep 2020 16:11:50
	System	26 Sep 2020 16:11:50

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cf6b0cc9-aaa9-4b0e-a5b2-e92b31ab9550' User entered 'No (N)'	System	26 Sep 2020 16:11:50
	System	26 Sep 2020 16:11:50

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-26T12:11:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cf6b0cc9-aaa9-4b0e-a5b2-e92b31ab9550' User entered '26 Sep 2020 12:11'	System	26 Sep 2020 16:11:50
	System	26 Sep 2020 16:11:50

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 6'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:40:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9cf51e58-d3f8-4691-9c0e-fc753e58bf59' User entered 'None (0)'	System	28 Sep 2020 11:41:25
	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:41:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9cf51e58-d3f8-4691-9c0e-fc753e58bf59' User entered 'None (0)'	System	28 Sep 2020 11:41:25
	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:41:05', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9cf51e58-d3f8-4691-9c0e-fc753e58bf59'	System	28 Sep 2020 11:41:25
User entered 'No interference with activity (1)'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:41:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9cf51e58-d3f8-4691-9c0e-fc753e58bf59'	System	28 Sep 2020 11:41:25
User entered 'No interference with activity (1)'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:41:12', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9cf51e58-d3f8-4691-9c0e-fc753e58bf59' User entered 'None (0)'	System	28 Sep 2020 11:41:25
	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:41:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9cf51e58-d3f8-4691-9c0e-fc753e58bf59' User entered 'None (0)'	System	28 Sep 2020 11:41:25
	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:41:19', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9cf51e58-d3f8-4691-9c0e-fc753e58bf59' User entered 'No (N)'	System	28 Sep 2020 11:41:25
	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-28T07:41:22', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9cf51e58-d3f8-4691-9c0e-fc753e58bf59' User entered '28 Sep 2020 07:41'	System	28 Sep 2020 11:41:25
	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Sep 2020 17:04:08
User entered 'Day 7'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:36', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880e8d35-43b8-41bc-978c-c5b9219a1da7' User entered 'None (0)'	System	29 Sep 2020 10:02:13
	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880e8d35-43b8-41bc-978c-c5b9219a1da7' User entered 'None (0)'	System	29 Sep 2020 10:02:13
	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880e8d35-43b8-41bc-978c-c5b9219a1da7'	System	29 Sep 2020 10:02:13
User entered 'No interference with activity (1)'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880e8d35-43b8-41bc-978c-c5b9219a1da7'	System	29 Sep 2020 10:02:13
User entered 'No interference with activity (1)'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:01:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880e8d35-43b8-41bc-978c-c5b9219a1da7' User entered 'None (0)'	System	29 Sep 2020 10:02:13
	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:02:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880e8d35-43b8-41bc-978c-c5b9219a1da7' User entered 'None (0)'	System	29 Sep 2020 10:02:13
	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:02:07', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880e8d35-43b8-41bc-978c-c5b9219a1da7' User entered 'No (N)'	System	29 Sep 2020 10:02:13
	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T06:02:11', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '880e8d35-43b8-41bc-978c-c5b9219a1da7' User entered '29 Sep 2020 06:02'	System	29 Sep 2020 10:02:13
	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:04:08

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	28 Sep 2020 11:41:25
User entered 'Day 8'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T12:00:31', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '19e098a3-7e86-47db-8243-4539fea05fed'	System	29 Sep 2020 16:00:48
User entered 'No interference with activity (1)'	System	29 Sep 2020 16:00:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T12:00:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '19e098a3-7e86-47db-8243-4539fea05fed' User entered '29 Sep 2020 12:00'	System	29 Sep 2020 16:00:48
	System	29 Sep 2020 16:00:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	29 Sep 2020 10:02:13
User entered 'Day 9'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-30T16:46:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'bc4f4d9e-f284-4912-a432-0e5cb183e5f3'	System	30 Sep 2020 20:46:30
User entered 'No interference with activity (1)'	System	30 Sep 2020 20:46:30

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-30T16:46:25', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'bc4f4d9e-f284-4912-a432-0e5cb183e5f3'	System	30 Sep 2020 20:46:30
User entered '30 Sep 2020 16:46'	System	30 Sep 2020 20:46:30

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	29 Sep 2020 16:00:48
User entered 'Day 10'	System	29 Sep 2020 16:00:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-01T20:35:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '82a1a9c7-ca2b-4551-b132-d8cc2d099d3c'	System	02 Oct 2020 00:35:24
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:35:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-01T20:35:21', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '82a1a9c7-ca2b-4551-b132-d8cc2d099d3c' User entered '01 Oct 2020 20:35'	System	02 Oct 2020 00:35:24
	System	02 Oct 2020 00:35:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:00:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:00:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Sep 2020 20:46:30
User entered 'Day 11'	System	30 Sep 2020 20:46:30

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-02T23:59:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'bfa04953-0a6f-4453-80f7-8c694eada789'	System	03 Oct 2020 03:59:49
User entered 'No interference with activity (1)'	System	03 Oct 2020 03:59:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-02T23:59:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'bfa04953-0a6f-4453-80f7-8c694eada789' User entered '02 Oct 2020 23:59'	System	03 Oct 2020 03:59:49
	System	03 Oct 2020 03:59:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:46:30

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:46:30

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	02 Oct 2020 00:35:24
User entered 'Day 12'	System	02 Oct 2020 00:35:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-03T13:47:40', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1ea7a647-2433-48b3-a849-b2677c825bcc' User entered 'No interference with activity (1)'	System	03 Oct 2020 17:47:47
	System	03 Oct 2020 17:47:47

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-03T13:47:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1ea7a647-2433-48b3-a849-b2677c825bcc' User entered '03 Oct 2020 13:47'	System	03 Oct 2020 17:47:47
	System	03 Oct 2020 17:47:47

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 00:35:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 00:35:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Oct 2020 03:59:49
User entered 'Day 13'	System	03 Oct 2020 03:59:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-04T12:05:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '74d69a6b-76af-4d51-bef1-7eb2c04edf7e' User entered 'No interference with activity (1)'	System	04 Oct 2020 16:06:08
	System	04 Oct 2020 16:06:08

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-04T12:06:01', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '74d69a6b-76af-4d51-bef1-7eb2c04edf7e' User entered '04 Oct 2020 12:06'	System	04 Oct 2020 16:06:08
	System	04 Oct 2020 16:06:08

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 03:59:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 03:59:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Oct 2020 17:47:47
User entered 'Day 14'	System	03 Oct 2020 17:47:47

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-05T12:03:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0bebfed8-0e83-4693-9625-475e3c1b183a'	System	05 Oct 2020 16:03:52
User entered 'No interference with activity (1)'	System	05 Oct 2020 16:03:52

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-05T12:03:04', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0bebfed8-0e83-4693-9625-475e3c1b183a' User entered '05 Oct 2020 12:03'	System	05 Oct 2020 16:03:52
	System	05 Oct 2020 16:03:52

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 17:47:47

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 17:47:47

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Oct 2020 16:06:08
User entered 'Day 15'	System	04 Oct 2020 16:06:08

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-06T23:59:39', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cdf2d6cf-9ce8-4817-be54-2bdae8fbdee0' User entered 'No interference with activity (1)'	System	07 Oct 2020 03:59:46
	System	07 Oct 2020 03:59:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-06T23:59:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cdf2d6cf-9ce8-4817-be54-2bdae8fbdee0' User entered '06 Oct 2020 23:59'	System	07 Oct 2020 03:59:46
	System	07 Oct 2020 03:59:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 16:06:08

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 16:06:08

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	05 Oct 2020 16:03:52
User entered 'Day 16'	System	05 Oct 2020 16:03:52

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-07T13:44:35', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '16ee287d-b5b0-4d2f-927c-926ab83cec4d' User entered 'No interference with activity (1)'	System	07 Oct 2020 17:44:42
	System	07 Oct 2020 17:44:42

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-07T13:44:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '16ee287d-b5b0-4d2f-927c-926ab83cec4d' User entered '07 Oct 2020 13:44'	System	07 Oct 2020 17:44:42
	System	07 Oct 2020 17:44:42

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 16:03:52

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 16:03:52

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Oct 2020 03:59:46
User entered 'Day 17'	System	07 Oct 2020 03:59:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-08T12:00:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9d9460ac-3a6c-4de8-a2b5-be01f6c8dccc' User entered 'No interference with activity (1)'	System	08 Oct 2020 16:00:58
	System	08 Oct 2020 16:00:58

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-08T12:00:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9d9460ac-3a6c-4de8-a2b5-be01f6c8dccc' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 16:00:58
	System	08 Oct 2020 16:00:58

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 03:59:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 03:59:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Oct 2020 17:44:42
User entered 'Day 18'	System	07 Oct 2020 17:44:42

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-09T12:27:05', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba4664e1-7742-49af-896d-3644137617a0'	System	09 Oct 2020 16:27:11
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:27:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-09T12:27:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ba4664e1-7742-49af-896d-3644137617a0' User entered '09 Oct 2020 12:27'	System	09 Oct 2020 16:27:11
	System	09 Oct 2020 16:27:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:44:42

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:44:42

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	08 Oct 2020 16:00:58
User entered 'Day 19'	System	08 Oct 2020 16:00:58

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-10T12:00:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8924437d-05a5-4137-8c0c-ff4a36250f2d'	System	10 Oct 2020 16:01:07
User entered 'No interference with activity (1)'	System	10 Oct 2020 16:01:07

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-10T12:00:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8924437d-05a5-4137-8c0c-ff4a36250f2d' User entered '10 Oct 2020 12:00'	System	10 Oct 2020 16:01:07
	System	10 Oct 2020 16:01:07

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:00:58

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:00:58

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	09 Oct 2020 16:27:11
User entered 'Day 20'	System	09 Oct 2020 16:27:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-11T12:00:55', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5b8792e4-3abd-4399-9ff2-d40f4b74cf8e' User entered 'No interference with activity (1)'	System	11 Oct 2020 16:01:26
	System	11 Oct 2020 16:01:26

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-11T12:00:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5b8792e4-3abd-4399-9ff2-d40f4b74cf8e' User entered '11 Oct 2020 12:00'	System	11 Oct 2020 16:01:26
	System	11 Oct 2020 16:01:26

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:27:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:27:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Oct 2020 16:01:07
User entered 'Day 21'	System	10 Oct 2020 16:01:07

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T00:00:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7007ab47-b27c-4fef-8d3c-4564ffc3a6c7'	System	13 Oct 2020 04:00:15
User entered 'No interference with activity (1)'	System	13 Oct 2020 04:00:15

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T00:00:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7007ab47-b27c-4fef-8d3c-4564ffc3a6c7' User entered '13 Oct 2020 00:00'	System	13 Oct 2020 04:00:15
	System	13 Oct 2020 04:00:15

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 16:01:07

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 16:01:07

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	11 Oct 2020 16:01:26
User entered 'Day 22'	System	11 Oct 2020 16:01:26

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T12:00:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0a785e74-4f05-426c-9e1d-a0ae72e3d974'	System	13 Oct 2020 16:01:24
User entered 'No interference with activity (1)'	System	13 Oct 2020 16:01:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T12:00:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0a785e74-4f05-426c-9e1d-a0ae72e3d974' User entered '13 Oct 2020 12:00'	System	13 Oct 2020 16:01:24
	System	13 Oct 2020 16:01:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 16:01:26

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 16:01:26

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	13 Oct 2020 04:00:15
User entered 'Day 23'	System	13 Oct 2020 04:00:15

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-14T12:01:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4af93884-897f-47e1-b2ea-8d7f24714b74'	System	14 Oct 2020 16:02:51
User entered 'No interference with activity (1)'	System	14 Oct 2020 16:02:51

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-14T12:01:55', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4af93884-897f-47e1-b2ea-8d7f24714b74' User entered '14 Oct 2020 12:01'	System	14 Oct 2020 16:02:51
	System	14 Oct 2020 16:02:51

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 04:00:15

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 04:00:15

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	13 Oct 2020 16:01:24
User entered 'Day 24'	System	13 Oct 2020 16:01:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-15T13:21:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '91e31309-efde-4160-89f0-69301ec12421'	System	15 Oct 2020 17:21:46
User entered 'No interference with activity (1)'	System	15 Oct 2020 17:21:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-15T13:21:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '91e31309-efde-4160-89f0-69301ec12421' User entered '15 Oct 2020 13:21'	System	15 Oct 2020 17:21:46
	System	15 Oct 2020 17:21:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:01:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:01:24

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	14 Oct 2020 16:02:51
User entered 'Day 25'	System	14 Oct 2020 16:02:51

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-16T12:01:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6547e190-92a4-4248-9c7f-876c02bcfa88'	System	16 Oct 2020 16:02:02
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:02:02

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-16T12:01:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6547e190-92a4-4248-9c7f-876c02bcfa88' User entered '16 Oct 2020 12:01'	System	16 Oct 2020 16:02:02
	System	16 Oct 2020 16:02:02

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:02:51

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:02:51

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	15 Oct 2020 17:21:46
User entered 'Day 26'	System	15 Oct 2020 17:21:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T08:29:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f3bc72f0-f8d8-4028-a0d5-85d6e415cc48'	System	18 Oct 2020 12:30:00
User entered 'No interference with activity (1)'	System	18 Oct 2020 12:30:00

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T08:29:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f3bc72f0-f8d8-4028-a0d5-85d6e415cc48' User entered '18 Oct 2020 08:29'	System	18 Oct 2020 12:30:00
	System	18 Oct 2020 12:30:00

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:21:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:21:46

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	16 Oct 2020 16:02:02
User entered 'Day 27'	System	16 Oct 2020 16:02:02

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T12:44:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5e6ce92c-4da6-4d05-b39f-3b6266ef9474'	System	18 Oct 2020 16:44:49
User entered 'No interference with activity (1)'	System	18 Oct 2020 16:44:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T12:44:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5e6ce92c-4da6-4d05-b39f-3b6266ef9474' User entered '18 Oct 2020 12:44'	System	18 Oct 2020 16:44:49
	System	18 Oct 2020 16:44:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:02:02

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:02:02

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	18 Oct 2020 12:30:00
User entered 'Day 28'	System	18 Oct 2020 12:30:00

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T06:00:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7333092b-74b9-433e-a40c-2e6d795cf82e'	System	20 Oct 2020 10:00:43
User entered 'No interference with activity (1)'	System	20 Oct 2020 10:00:43

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T06:00:40', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7333092b-74b9-433e-a40c-2e6d795cf82e' User entered '20 Oct 2020 06:00'	System	20 Oct 2020 10:00:43
	System	20 Oct 2020 10:00:43

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 12:30:00

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 12:30:00

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	18 Oct 2020 16:44:49
User entered 'Day 29'	System	18 Oct 2020 16:44:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T12:01:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'dde33962-f4e5-4476-8dbc-14541104a6a1'	System	20 Oct 2020 16:02:17
User entered 'No interference with activity (1)'	System	20 Oct 2020 16:02:17

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T12:01:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'dde33962-f4e5-4476-8dbc-14541104a6a1' User entered '20 Oct 2020 12:01'	System	20 Oct 2020 16:02:17
	System	20 Oct 2020 16:02:17

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 16:44:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 16:44:49

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	20 Oct 2020 10:00:43
User entered 'Day 30'	System	20 Oct 2020 10:00:43

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-21T23:59:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '01bee152-5c02-4780-a36a-0eb45ec61110'	System	22 Oct 2020 04:00:05
User entered 'No interference with activity (1)'	System	22 Oct 2020 04:00:05

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-21T23:59:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '01bee152-5c02-4780-a36a-0eb45ec61110' User entered '21 Oct 2020 23:59'	System	22 Oct 2020 04:00:05
	System	22 Oct 2020 04:00:05

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 10:00:43

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 10:00:43

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	20 Oct 2020 16:02:17
User entered 'Day 31'	System	20 Oct 2020 16:02:17

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T08:48:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd085804c-106d-4e41-a252-224786acb9a5' User entered 'No interference with activity (1)'	System	23 Oct 2020 12:48:25
	System	23 Oct 2020 12:48:25

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T08:48:23', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd085804c-106d-4e41-a252-224786acb9a5' User entered '23 Oct 2020 08:48'	System	23 Oct 2020 12:48:25
	System	23 Oct 2020 12:48:25

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:02:17

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:02:17

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Oct 2020 04:00:05
User entered 'Day 32'	System	22 Oct 2020 04:00:05

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T23:59:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '195947ec-ea7f-4b1a-bd64-060a9941030d' User entered 'No interference with activity (1)'	System	24 Oct 2020 03:59:41
	System	24 Oct 2020 03:59:41

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T23:59:39', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '195947ec-ea7f-4b1a-bd64-060a9941030d' User entered '23 Oct 2020 23:59'	System	24 Oct 2020 03:59:41
	System	24 Oct 2020 03:59:41

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 04:00:05

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 04:00:05

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	23 Oct 2020 12:48:25
User entered 'Day 33'	System	23 Oct 2020 12:48:25

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:07:23', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a501c45c-d184-4737-a840-430fb6efb7e0'	System	24 Oct 2020 17:07:31
User entered 'No interference with activity (1)'	System	24 Oct 2020 17:07:31

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:07:28', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a501c45c-d184-4737-a840-430fb6efb7e0' User entered '24 Oct 2020 13:07'	System	24 Oct 2020 17:07:31
	System	24 Oct 2020 17:07:31

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 12:48:25

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 12:48:25

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Oct 2020 03:59:41
User entered 'Day 34'	System	24 Oct 2020 03:59:41

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-25T12:00:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'af157d99-0692-4846-bfd8-2c875ecc070b' User entered 'No interference with activity (1)'	System	25 Oct 2020 16:00:38
	System	25 Oct 2020 16:00:38

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-25T12:00:32', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'af157d99-0692-4846-bfd8-2c875ecc070b' User entered '25 Oct 2020 12:00'	System	25 Oct 2020 16:00:38
	System	25 Oct 2020 16:00:38

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:59:41

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:59:41

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Oct 2020 17:07:31
User entered 'Day 35'	System	24 Oct 2020 17:07:31

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-26T13:18:23', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '04e7c48b-4f2c-4dde-a732-6db9183a4682'	System	26 Oct 2020 17:18:28
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:18:28

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-26T13:18:26', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '04e7c48b-4f2c-4dde-a732-6db9183a4682' User entered '26 Oct 2020 13:18'	System	26 Oct 2020 17:18:28
	System	26 Oct 2020 17:18:28

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:07:31

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:07:31

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	25 Oct 2020 16:00:38
User entered 'Day 36'	System	25 Oct 2020 16:00:38

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-27T16:37:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e46811b4-ef78-4a40-9408-b74038d635cb'	System	27 Oct 2020 20:37:11
User entered 'No interference with activity (1)'	System	27 Oct 2020 20:37:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-27T16:37:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e46811b4-ef78-4a40-9408-b74038d635cb' User entered '27 Oct 2020 16:37'	System	27 Oct 2020 20:37:11
	System	27 Oct 2020 20:37:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 16:00:38

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 16:00:38

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	26 Oct 2020 17:18:28
User entered 'Day 37'	System	26 Oct 2020 17:18:28

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-28T12:00:52', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b74a9057-8f11-4b11-9341-98563af15164'	System	28 Oct 2020 16:01:21
User entered 'No interference with activity (1)'	System	28 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-28T12:00:55', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b74a9057-8f11-4b11-9341-98563af15164' User entered '28 Oct 2020 12:00'	System	28 Oct 2020 16:01:21
	System	28 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:18:28

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:18:28

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	27 Oct 2020 20:37:11
User entered 'Day 38'	System	27 Oct 2020 20:37:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T08:00:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9f4b2a30-70c0-4d39-8fc0-885cbfcf10fd' User entered 'No interference with activity (1)'	System	30 Oct 2020 12:01:06
	System	30 Oct 2020 12:01:06

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T08:01:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9f4b2a30-70c0-4d39-8fc0-885cbfcf10fd' User entered '30 Oct 2020 08:01'	System	30 Oct 2020 12:01:06
	System	30 Oct 2020 12:01:06

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 20:37:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 20:37:11

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	28 Oct 2020 16:01:21
User entered 'Day 39'	System	28 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T12:31:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5fa64512-028a-4541-a2a4-7d5029ea1c5a'	System	30 Oct 2020 16:31:50
User entered 'No interference with activity (1)'	System	30 Oct 2020 16:31:50

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T12:31:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5fa64512-028a-4541-a2a4-7d5029ea1c5a' User entered '30 Oct 2020 12:31'	System	30 Oct 2020 16:31:50
	System	30 Oct 2020 16:31:50

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Oct 2020 12:01:06
User entered 'Day 40'	System	30 Oct 2020 12:01:06

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T07:48:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '399c8cf9-a46f-436a-9b2b-eac2ae09dcf2' User entered 'No interference with activity (1)'	System	01 Nov 2020 12:48:18
	System	01 Nov 2020 12:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T07:48:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '399c8cf9-a46f-436a-9b2b-eac2ae09dcf2' User entered '01 Nov 2020 07:48'	System	01 Nov 2020 12:48:18
	System	01 Nov 2020 12:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 12:01:06

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 12:01:06

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Oct 2020 16:31:50
User entered 'Day 41'	System	30 Oct 2020 16:31:50

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T12:54:13', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b8b7b91a-7401-48d3-b5fa-fedad13a4b74'	System	01 Nov 2020 17:54:22
User entered 'No interference with activity (1)'	System	01 Nov 2020 17:54:22

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T12:54:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b8b7b91a-7401-48d3-b5fa-fedad13a4b74' User entered '01 Nov 2020 12:54'	System	01 Nov 2020 17:54:22
	System	01 Nov 2020 17:54:22

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 16:31:50

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 16:31:50

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Nov 2020 12:48:18
User entered 'Day 42'	System	01 Nov 2020 12:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 12:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 12:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Nov 2020 17:54:22
User entered 'Day 43'	System	01 Nov 2020 17:54:22

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-04T00:00:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '28e9ea99-9b82-4e8e-9030-645185ad8bb7'	System	04 Nov 2020 05:00:21
User entered 'No interference with activity (1)'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-04T00:00:19', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '28e9ea99-9b82-4e8e-9030-645185ad8bb7' User entered '04 Nov 2020 00:00'	System	04 Nov 2020 05:00:21
	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 17:54:22

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 17:54:22

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Nov 2020 05:00:21
User entered 'Day 44'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Nov 2020 05:00:21
User entered 'Day 45'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	28 Sep 2020 11:41:25
User entered 'Day 8'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T12:00:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0a028de4-d429-4d2c-af12-4747e71f58b3' User entered 'No interference with activity (1)'	System	29 Sep 2020 16:01:14
	System	29 Sep 2020 16:01:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T12:00:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0a028de4-d429-4d2c-af12-4747e71f58b3' User entered '29 Sep 2020 12:00'	System	29 Sep 2020 16:01:14
	System	29 Sep 2020 16:01:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	29 Sep 2020 10:02:13
User entered 'Day 9'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-30T16:46:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'bfe7c6f3-d6ad-4b3b-a468-7467f42e4711'	System	30 Sep 2020 20:46:41
User entered 'No interference with activity (1)'	System	30 Sep 2020 20:46:41

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-30T16:46:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'bfe7c6f3-d6ad-4b3b-a468-7467f42e4711' User entered '30 Sep 2020 16:46'	System	30 Sep 2020 20:46:41
	System	30 Sep 2020 20:46:41

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	29 Sep 2020 16:01:14
User entered 'Day 10'	System	29 Sep 2020 16:01:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-01T20:35:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e771fc81-8ca3-42bd-8122-2ac22700ec7b' User entered 'No interference with activity (1)'	System	02 Oct 2020 00:35:33
	System	02 Oct 2020 00:35:33

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-01T20:35:31', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e771fc81-8ca3-42bd-8122-2ac22700ec7b' User entered '01 Oct 2020 20:35'	System	02 Oct 2020 00:35:33
	System	02 Oct 2020 00:35:33

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:01:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:01:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Sep 2020 20:46:41
User entered 'Day 11'	System	30 Sep 2020 20:46:41

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-02T23:59:54', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a7db533d-ba5e-4064-860a-6323770f3abc' User entered 'No interference with activity (1)'	System	03 Oct 2020 04:00:01
	System	03 Oct 2020 04:00:01

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-02T23:59:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a7db533d-ba5e-4064-860a-6323770f3abc' User entered '02 Oct 2020 23:59'	System	03 Oct 2020 04:00:01
	System	03 Oct 2020 04:00:01

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:46:41

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:46:41

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	02 Oct 2020 00:35:33
User entered 'Day 12'	System	02 Oct 2020 00:35:33

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-03T13:47:54', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '62b47e61-d000-470e-b063-425dde58147c'	System	03 Oct 2020 17:48:00
User entered 'No interference with activity (1)'	System	03 Oct 2020 17:48:00

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-03T13:47:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '62b47e61-d000-470e-b063-425dde58147c' User entered '03 Oct 2020 13:47'	System	03 Oct 2020 17:48:00
	System	03 Oct 2020 17:48:00

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 00:35:33

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 00:35:33

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Oct 2020 04:00:01
User entered 'Day 13'	System	03 Oct 2020 04:00:01

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-04T12:06:07', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e62d72ec-f71b-4f6a-b4c4-21495316eea7'	System	04 Oct 2020 16:06:12
User entered 'No interference with activity (1)'	System	04 Oct 2020 16:06:12

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-04T12:06:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e62d72ec-f71b-4f6a-b4c4-21495316eea7' User entered '04 Oct 2020 12:06'	System	04 Oct 2020 16:06:12
	System	04 Oct 2020 16:06:12

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 04:00:01

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 04:00:01

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Oct 2020 17:48:00
User entered 'Day 14'	System	03 Oct 2020 17:48:00

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-05T12:03:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e7c10430-db59-4758-aa0c-d29dcbc9ddc5'	System	05 Oct 2020 16:03:58
User entered 'No interference with activity (1)'	System	05 Oct 2020 16:03:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-05T12:03:18', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e7c10430-db59-4758-aa0c-d29dcbc9ddc5' User entered '05 Oct 2020 12:03'	System	05 Oct 2020 16:03:58
	System	05 Oct 2020 16:03:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 17:48:00

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 17:48:00

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Oct 2020 16:06:12
User entered 'Day 15'	System	04 Oct 2020 16:06:12

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-06T23:59:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2fd14ad4-80fe-4725-84f8-f1466d9389e6'	System	07 Oct 2020 03:59:51
User entered 'No interference with activity (1)'	System	07 Oct 2020 03:59:51

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-06T23:59:50', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2fd14ad4-80fe-4725-84f8-f1466d9389e6' User entered '06 Oct 2020 23:59'	System	07 Oct 2020 03:59:51
	System	07 Oct 2020 03:59:51

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 16:06:12

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 16:06:12

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	05 Oct 2020 16:03:58
User entered 'Day 16'	System	05 Oct 2020 16:03:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-07T13:44:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b4e1124a-64b2-4d3b-a381-639a95ce0bb8' User entered 'No interference with activity (1)'	System	07 Oct 2020 17:44:52
	System	07 Oct 2020 17:44:52

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-07T13:44:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b4e1124a-64b2-4d3b-a381-639a95ce0bb8' User entered '07 Oct 2020 13:44'	System	07 Oct 2020 17:44:52
	System	07 Oct 2020 17:44:52

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 16:03:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 16:03:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Oct 2020 03:59:51
User entered 'Day 17'	System	07 Oct 2020 03:59:51

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-08T12:00:50', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '73886799-6222-47d4-99ae-375e603d72bd'	System	08 Oct 2020 16:01:21
User entered 'No interference with activity (1)'	System	08 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-08T12:00:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '73886799-6222-47d4-99ae-375e603d72bd' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 16:01:21
	System	08 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 03:59:51

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 03:59:51

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Oct 2020 17:44:52
User entered 'Day 18'	System	07 Oct 2020 17:44:52

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-09T12:27:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5feacfc1-fa59-4a4f-bb65-4aa4c884a438'	System	09 Oct 2020 16:27:23
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:27:23

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-09T12:27:19', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5feacfc1-fa59-4a4f-bb65-4aa4c884a438' User entered '09 Oct 2020 12:27'	System	09 Oct 2020 16:27:23
	System	09 Oct 2020 16:27:23

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:44:52

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:44:52

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	08 Oct 2020 16:01:21
User entered 'Day 19'	System	08 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-10T12:02:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4b932131-670e-4f92-8f97-3ad1ad36579b' User entered 'No interference with activity (1)'	System	10 Oct 2020 16:02:18
	System	10 Oct 2020 16:02:18

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-10T12:02:14', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4b932131-670e-4f92-8f97-3ad1ad36579b' User entered '10 Oct 2020 12:02'	System	10 Oct 2020 16:02:18
	System	10 Oct 2020 16:02:18

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	09 Oct 2020 16:27:23
User entered 'Day 20'	System	09 Oct 2020 16:27:23

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-11T12:01:04', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2b302bb6-1af0-42fa-9fe9-31484cb727ac'	System	11 Oct 2020 16:01:45
User entered 'No interference with activity (1)'	System	11 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-11T12:01:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2b302bb6-1af0-42fa-9fe9-31484cb727ac' User entered '11 Oct 2020 12:01'	System	11 Oct 2020 16:01:45
	System	11 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:27:23

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:27:23

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Oct 2020 16:02:18
User entered 'Day 21'	System	10 Oct 2020 16:02:18

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T00:00:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b2a54252-2979-44fd-9bc2-a70478a862bd' User entered 'No interference with activity (1)'	System	13 Oct 2020 04:00:24
	System	13 Oct 2020 04:00:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T00:00:19', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b2a54252-2979-44fd-9bc2-a70478a862bd' User entered '13 Oct 2020 00:00'	System	13 Oct 2020 04:00:24
	System	13 Oct 2020 04:00:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 16:02:18

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 16:02:18

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	11 Oct 2020 16:01:45
User entered 'Day 22'	System	11 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T12:00:54', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '314d503d-af5a-49f4-a33e-1177cbcd663e' User entered 'No interference with activity (1)'	System	13 Oct 2020 16:01:45
	System	13 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T12:01:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '314d503d-af5a-49f4-a33e-1177cbcd663e' User entered '13 Oct 2020 12:01'	System	13 Oct 2020 16:01:45
	System	13 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	13 Oct 2020 04:00:24
User entered 'Day 23'	System	13 Oct 2020 04:00:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-14T12:01:59', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cafae53e-f93f-4788-b987-647a97f15d70'	System	14 Oct 2020 16:03:09
User entered 'No interference with activity (1)'	System	14 Oct 2020 16:03:09

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-14T12:02:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'cafae53e-f93f-4788-b987-647a97f15d70' User entered '14 Oct 2020 12:02'	System	14 Oct 2020 16:03:09
	System	14 Oct 2020 16:03:09

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 04:00:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 04:00:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	13 Oct 2020 16:01:45
User entered 'Day 24'	System	13 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-15T13:21:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'adc5b945-2c3d-44aa-a653-2f49f7d2e04b' User entered 'No interference with activity (1)'	System	15 Oct 2020 17:21:56
	System	15 Oct 2020 17:21:56

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-15T13:21:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'adc5b945-2c3d-44aa-a653-2f49f7d2e04b' User entered '15 Oct 2020 13:21'	System	15 Oct 2020 17:21:56
	System	15 Oct 2020 17:21:56

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:01:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	14 Oct 2020 16:03:09
User entered 'Day 25'	System	14 Oct 2020 16:03:09

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-16T12:01:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '930c4cdb-b03c-4e0c-9f73-3a64ad4a9c87'	System	16 Oct 2020 16:02:40
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:02:40

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-16T12:01:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '930c4cdb-b03c-4e0c-9f73-3a64ad4a9c87' User entered '16 Oct 2020 12:01'	System	16 Oct 2020 16:02:40
	System	16 Oct 2020 16:02:40

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:03:09

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:03:09

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	15 Oct 2020 17:21:56
User entered 'Day 26'	System	15 Oct 2020 17:21:56

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T08:30:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '99acaec5-a07f-4741-8e2e-ec4e371f7b7c' User entered 'No interference with activity (1)'	System	18 Oct 2020 12:30:11
	System	18 Oct 2020 12:30:11

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T08:30:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '99acaec5-a07f-4741-8e2e-ec4e371f7b7c' User entered '18 Oct 2020 08:30'	System	18 Oct 2020 12:30:11
	System	18 Oct 2020 12:30:11

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:21:56

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:21:56

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	16 Oct 2020 16:02:40
User entered 'Day 27'	System	16 Oct 2020 16:02:40

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T12:44:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6ba639d7-c008-4fc9-925e-82b9766fa3bf' User entered 'No interference with activity (1)'	System	18 Oct 2020 16:44:57
	System	18 Oct 2020 16:44:57

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T12:44:54', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6ba639d7-c008-4fc9-925e-82b9766fa3bf' User entered '18 Oct 2020 12:44'	System	18 Oct 2020 16:44:57
	System	18 Oct 2020 16:44:57

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:02:40

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:02:40

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	18 Oct 2020 12:30:11
User entered 'Day 28'	System	18 Oct 2020 12:30:11

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T06:01:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5031e79d-fa13-47e0-83e6-03bcd515d630'	System	20 Oct 2020 10:01:08
User entered 'No interference with activity (1)'	System	20 Oct 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T06:01:05', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '5031e79d-fa13-47e0-83e6-03bcd515d630' User entered '20 Oct 2020 06:01'	System	20 Oct 2020 10:01:08
	System	20 Oct 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 12:30:11

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 12:30:11

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	18 Oct 2020 16:44:57
User entered 'Day 29'	System	18 Oct 2020 16:44:57

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T12:01:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1beae735-9361-44cf-a7da-b81686b187d9'	System	20 Oct 2020 16:02:29
User entered 'No interference with activity (1)'	System	20 Oct 2020 16:02:29

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T12:01:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1beae735-9361-44cf-a7da-b81686b187d9' User entered '20 Oct 2020 12:01'	System	20 Oct 2020 16:02:29
	System	20 Oct 2020 16:02:29

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 16:44:57

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 16:44:57

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	20 Oct 2020 10:01:08
User entered 'Day 30'	System	20 Oct 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-22T00:00:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8358f897-9521-4d7e-8a41-56dd92831c34'	System	22 Oct 2020 04:00:14
User entered 'No interference with activity (1)'	System	22 Oct 2020 04:00:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-22T00:00:11', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8358f897-9521-4d7e-8a41-56dd92831c34' User entered '22 Oct 2020 00:00'	System	22 Oct 2020 04:00:14
	System	22 Oct 2020 04:00:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 10:01:08

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	20 Oct 2020 16:02:29
User entered 'Day 31'	System	20 Oct 2020 16:02:29

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T08:48:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '51966302-aa0e-488b-bf3d-7b063c327892'	System	23 Oct 2020 12:48:36
User entered 'No interference with activity (1)'	System	23 Oct 2020 12:48:36

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T08:48:32', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '51966302-aa0e-488b-bf3d-7b063c327892' User entered '23 Oct 2020 08:48'	System	23 Oct 2020 12:48:36
	System	23 Oct 2020 12:48:36

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:02:29

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:02:29

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Oct 2020 04:00:14
User entered 'Day 32'	System	22 Oct 2020 04:00:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T23:59:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'dbab771f-f448-46e4-9bb8-c3cde7625eee' User entered 'No interference with activity (1)'	System	24 Oct 2020 03:59:50
	System	24 Oct 2020 03:59:50

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T23:59:47', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'dbab771f-f448-46e4-9bb8-c3cde7625eee' User entered '23 Oct 2020 23:59'	System	24 Oct 2020 03:59:50
	System	24 Oct 2020 03:59:50

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 04:00:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 04:00:14

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	23 Oct 2020 12:48:36
User entered 'Day 33'	System	23 Oct 2020 12:48:36

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:07:36', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fe368232-e9b6-4fe0-a4d6-d52bbbed890d' User entered 'No interference with activity (1)'	System	24 Oct 2020 17:07:45
	System	24 Oct 2020 17:07:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:07:40', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fe368232-e9b6-4fe0-a4d6-d52bbbed890d' User entered '24 Oct 2020 13:07'	System	24 Oct 2020 17:07:45
	System	24 Oct 2020 17:07:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 12:48:36

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 12:48:36

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Oct 2020 03:59:50
User entered 'Day 34'	System	24 Oct 2020 03:59:50

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-25T12:00:38', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '613dbc4c-1b6b-4a65-b612-8e96475223fa' User entered 'No interference with activity (1)'	System	25 Oct 2020 16:00:44
	System	25 Oct 2020 16:00:44

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-25T12:00:42', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '613dbc4c-1b6b-4a65-b612-8e96475223fa' User entered '25 Oct 2020 12:00'	System	25 Oct 2020 16:00:44
	System	25 Oct 2020 16:00:44

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:59:50

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:59:50

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Oct 2020 17:07:45
User entered 'Day 35'	System	24 Oct 2020 17:07:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-26T13:18:32', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '193c1bb9-9211-44f5-ab61-4b612c0b5734'	System	26 Oct 2020 17:18:38
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:18:38

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-26T13:18:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '193c1bb9-9211-44f5-ab61-4b612c0b5734' User entered '26 Oct 2020 13:18'	System	26 Oct 2020 17:18:38
	System	26 Oct 2020 17:18:38

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:07:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:07:45

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	25 Oct 2020 16:00:44
User entered 'Day 36'	System	25 Oct 2020 16:00:44

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-27T16:37:14', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f0dd6113-fafe-4f18-a07b-d2c7bac297ab' User entered 'No interference with activity (1)'	System	27 Oct 2020 20:37:24
	System	27 Oct 2020 20:37:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-27T16:37:18', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f0dd6113-fafe-4f18-a07b-d2c7bac297ab' User entered '27 Oct 2020 16:37'	System	27 Oct 2020 20:37:24
	System	27 Oct 2020 20:37:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 16:00:44

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 16:00:44

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	26 Oct 2020 17:18:38
User entered 'Day 37'	System	26 Oct 2020 17:18:38

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-28T12:01:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f8553d22-ab57-4ca3-bc4d-7211a9015d6a' User entered 'No interference with activity (1)'	System	28 Oct 2020 16:01:37
	System	28 Oct 2020 16:01:37

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-28T12:01:04', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f8553d22-ab57-4ca3-bc4d-7211a9015d6a' User entered '28 Oct 2020 12:01'	System	28 Oct 2020 16:01:37
	System	28 Oct 2020 16:01:37

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:18:38

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:18:38

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	27 Oct 2020 20:37:24
User entered 'Day 38'	System	27 Oct 2020 20:37:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T08:01:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'dd53c027-e6c8-47e4-b53b-dc6da1840e11'	System	30 Oct 2020 12:01:17
User entered 'No interference with activity (1)'	System	30 Oct 2020 12:01:17

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T08:01:12', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'dd53c027-e6c8-47e4-b53b-dc6da1840e11' User entered '30 Oct 2020 08:01'	System	30 Oct 2020 12:01:17
	System	30 Oct 2020 12:01:17

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 20:37:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 20:37:24

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	28 Oct 2020 16:01:37
User entered 'Day 39'	System	28 Oct 2020 16:01:37

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T12:31:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'acb48861-10e8-479c-814d-94cd51c9543c' User entered 'No interference with activity (1)'	System	30 Oct 2020 16:31:58
	System	30 Oct 2020 16:31:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T12:31:54', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'acb48861-10e8-479c-814d-94cd51c9543c' User entered '30 Oct 2020 12:31'	System	30 Oct 2020 16:31:58
	System	30 Oct 2020 16:31:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 16:01:37

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 16:01:37

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Oct 2020 12:01:17
User entered 'Day 40'	System	30 Oct 2020 12:01:17

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T07:48:22', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '98dac1c5-3313-47b6-a73a-8a56d9757e1e' User entered 'No interference with activity (1)'	System	01 Nov 2020 12:48:35
	System	01 Nov 2020 12:48:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T07:48:33', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '98dac1c5-3313-47b6-a73a-8a56d9757e1e' User entered '01 Nov 2020 07:48'	System	01 Nov 2020 12:48:35
	System	01 Nov 2020 12:48:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 12:01:17

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 12:01:17

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Oct 2020 16:31:58
User entered 'Day 41'	System	30 Oct 2020 16:31:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T12:54:22', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '02bc1870-950d-43ad-845c-f57bfe991c80'	System	01 Nov 2020 17:54:28
User entered 'No interference with activity (1)'	System	01 Nov 2020 17:54:28

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T12:54:25', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '02bc1870-950d-43ad-845c-f57bfe991c80' User entered '01 Nov 2020 12:54'	System	01 Nov 2020 17:54:28
	System	01 Nov 2020 17:54:28

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 16:31:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 16:31:58

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Nov 2020 12:48:35
User entered 'Day 42'	System	01 Nov 2020 12:48:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 12:48:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 12:48:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Nov 2020 17:54:28
User entered 'Day 43'	System	01 Nov 2020 17:54:28

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-04T00:00:26', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '168e5b52-44fb-44db-b6ff-56070b40706b' User entered 'No interference with activity (1)'	System	04 Nov 2020 05:00:35
	System	04 Nov 2020 05:00:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-04T00:00:30', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '168e5b52-44fb-44db-b6ff-56070b40706b' User entered '04 Nov 2020 00:00'	System	04 Nov 2020 05:00:35
	System	04 Nov 2020 05:00:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 17:54:28

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 17:54:28

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Nov 2020 05:00:35
User entered 'Day 44'	System	04 Nov 2020 05:00:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 05:00:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 05:00:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Nov 2020 05:00:35
User entered 'Day 45'	System	04 Nov 2020 05:00:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 05:00:35

US3222315

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 05:00:35

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	28 Sep 2020 11:41:25
User entered 'Day 8'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T12:01:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '332b725d-f300-4951-8c72-f57142be61fa' User entered 'No (N)'	System	29 Sep 2020 16:01:40
	System	29 Sep 2020 16:01:40

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-29T12:01:07', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '332b725d-f300-4951-8c72-f57142be61fa' User entered '29 Sep 2020 12:01'	System	29 Sep 2020 16:01:40
	System	29 Sep 2020 16:01:40

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 11:41:25

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	29 Sep 2020 10:02:13
User entered 'Day 9'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-30T16:46:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4d2dfeba-5db0-47aa-b58c-8e2dc37ebab7' User entered 'No (N)'	System	30 Sep 2020 20:46:52
	System	30 Sep 2020 20:46:52

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-09-30T16:46:50', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4d2dfeba-5db0-47aa-b58c-8e2dc37ebab7' User entered '30 Sep 2020 16:46'	System	30 Sep 2020 20:46:52
	System	30 Sep 2020 20:46:52

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 10:02:13

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	29 Sep 2020 16:00:48
User entered 'Day 10'	System	29 Sep 2020 16:00:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-01T20:35:41', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'be399dd7-da1d-4444-8650-411a6cb9b9b9' User entered 'No (N)'	System	02 Oct 2020 00:35:46
	System	02 Oct 2020 00:35:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-01T20:35:44', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'be399dd7-da1d-4444-8650-411a6cb9b9b9' User entered '01 Oct 2020 20:35'	System	02 Oct 2020 00:35:46
	System	02 Oct 2020 00:35:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:00:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:00:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Sep 2020 20:46:30
User entered 'Day 11'	System	30 Sep 2020 20:46:30

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-03T00:00:06', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '3c57c486-bb06-45f7-9097-83d8c0c91f70' User entered 'No (N)'	System	03 Oct 2020 04:00:16
	System	03 Oct 2020 04:00:16

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-03T00:00:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '3c57c486-bb06-45f7-9097-83d8c0c91f70' User entered '03 Oct 2020 00:00'	System	03 Oct 2020 04:00:16
	System	03 Oct 2020 04:00:16

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:46:30

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:46:30

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	02 Oct 2020 00:35:24
User entered 'Day 12'	System	02 Oct 2020 00:35:24

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-03T13:48:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd42b41ec-84e6-497a-ae8-d4ca90fc4ffb' User entered 'No (N)'	System	03 Oct 2020 17:48:18
	System	03 Oct 2020 17:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-03T13:48:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd42b41ec-84e6-497a-ae8-d4ca90fc4ffb' User entered '03 Oct 2020 13:48'	System	03 Oct 2020 17:48:18
	System	03 Oct 2020 17:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 00:35:24

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 00:35:24

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Oct 2020 03:59:49
User entered 'Day 13'	System	03 Oct 2020 03:59:49

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-04T12:06:18', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '727a6423-ab5e-49ab-8deb-4adcc6f61017' User entered 'No (N)'	System	04 Oct 2020 16:06:26
	System	04 Oct 2020 16:06:26

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-04T12:06:22', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '727a6423-ab5e-49ab-8deb-4adcc6f61017' User entered '04 Oct 2020 12:06'	System	04 Oct 2020 16:06:26
	System	04 Oct 2020 16:06:26

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 03:59:49

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 03:59:49

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	03 Oct 2020 17:47:47
User entered 'Day 14'	System	03 Oct 2020 17:47:47

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-05T12:03:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fa95f0b5-1705-4c70-9a04-dae7d0360c73' User entered 'No (N)'	System	05 Oct 2020 16:04:06
	System	05 Oct 2020 16:04:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-05T12:03:32', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'fa95f0b5-1705-4c70-9a04-dae7d0360c73' User entered '05 Oct 2020 12:03'	System	05 Oct 2020 16:04:06
	System	05 Oct 2020 16:04:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 17:47:47

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 17:47:47

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Oct 2020 16:06:08
User entered 'Day 15'	System	04 Oct 2020 16:06:08

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-06T23:59:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1db27fd-3453-45a0-827e-0e1fc34ef4d3' User entered 'No (N)'	System	07 Oct 2020 04:00:12
	System	07 Oct 2020 04:00:12

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-07T00:00:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd1db27fd-3453-45a0-827e-0e1fc34ef4d3' User entered '07 Oct 2020 00:00'	System	07 Oct 2020 04:00:12
	System	07 Oct 2020 04:00:12

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 16:06:08

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 16:06:08

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	05 Oct 2020 16:03:52
User entered 'Day 16'	System	05 Oct 2020 16:03:52

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-07T13:44:56', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4aab5d7b-3d7d-4634-9648-7b01e1f0276e' User entered 'No (N)'	System	07 Oct 2020 17:45:09
	System	07 Oct 2020 17:45:09

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-07T13:45:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '4aab5d7b-3d7d-4634-9648-7b01e1f0276e' User entered '07 Oct 2020 13:45'	System	07 Oct 2020 17:45:09
	System	07 Oct 2020 17:45:09

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 16:03:52

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 16:03:52

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Oct 2020 03:59:46
User entered 'Day 17'	System	07 Oct 2020 03:59:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-08T12:00:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '69fd5ecf-a2ee-4ba0-b791-635da3c2a9fa' User entered 'No (N)'	System	08 Oct 2020 16:01:39
	System	08 Oct 2020 16:01:39

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-08T12:01:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '69fd5ecf-a2ee-4ba0-b791-635da3c2a9fa' User entered '08 Oct 2020 12:01'	System	08 Oct 2020 16:01:39
	System	08 Oct 2020 16:01:39

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 03:59:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 03:59:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	07 Oct 2020 17:44:42
User entered 'Day 18'	System	07 Oct 2020 17:44:42

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-09T12:27:24', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8ba19035-ebd8-4eed-9b86-428dc89fabe6' User entered 'No (N)'	System	09 Oct 2020 16:27:35
	System	09 Oct 2020 16:27:35

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-09T12:27:28', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '8ba19035-ebd8-4eed-9b86-428dc89fabe6' User entered '09 Oct 2020 12:27'	System	09 Oct 2020 16:27:35
	System	09 Oct 2020 16:27:35

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:44:42

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:44:42

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	08 Oct 2020 16:00:58
User entered 'Day 19'	System	08 Oct 2020 16:00:58

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-10T12:02:23', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '601b38e8-d163-42e9-ba3c-2547ca564b03' User entered 'No (N)'	System	10 Oct 2020 16:02:35
	System	10 Oct 2020 16:02:35

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-10T12:02:28', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '601b38e8-d163-42e9-ba3c-2547ca564b03' User entered '10 Oct 2020 12:02'	System	10 Oct 2020 16:02:35
	System	10 Oct 2020 16:02:35

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:00:58

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:00:58

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	09 Oct 2020 16:27:11
User entered 'Day 20'	System	09 Oct 2020 16:27:11

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-11T12:01:15', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e481f734-b002-4c74-94a0-8bc673c3dca8' User entered 'No (N)'	System	11 Oct 2020 16:01:59
	System	11 Oct 2020 16:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-11T12:01:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'e481f734-b002-4c74-94a0-8bc673c3dca8' User entered '11 Oct 2020 12:01'	System	11 Oct 2020 16:01:59
	System	11 Oct 2020 16:01:59

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:27:11

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:27:11

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	10 Oct 2020 16:01:07
User entered 'Day 21'	System	10 Oct 2020 16:01:07

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T00:00:25', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f483aa70-08d1-45f1-bd3c-7c39601034b2' User entered 'No (N)'	System	13 Oct 2020 04:00:32
	System	13 Oct 2020 04:00:32

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T00:00:30', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'f483aa70-08d1-45f1-bd3c-7c39601034b2' User entered '13 Oct 2020 00:00'	System	13 Oct 2020 04:00:32
	System	13 Oct 2020 04:00:32

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 16:01:07

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 16:01:07

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	11 Oct 2020 16:01:26
User entered 'Day 22'	System	11 Oct 2020 16:01:26

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T12:01:07', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6113e4cb-ba9a-47b5-8323-8f69d5ca2b94' User entered 'No (N)'	System	13 Oct 2020 16:02:00
	System	13 Oct 2020 16:02:00

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-13T12:01:11', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6113e4cb-ba9a-47b5-8323-8f69d5ca2b94' User entered '13 Oct 2020 12:01'	System	13 Oct 2020 16:02:00
	System	13 Oct 2020 16:02:00

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 16:01:26

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 16:01:26

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	13 Oct 2020 04:00:15
User entered 'Day 23'	System	13 Oct 2020 04:00:15

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-14T12:02:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '776db471-c341-43b6-af14-68a4146ef1b0' User entered 'No (N)'	System	14 Oct 2020 16:03:20
	System	14 Oct 2020 16:03:20

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-14T12:02:13', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '776db471-c341-43b6-af14-68a4146ef1b0' User entered '14 Oct 2020 12:02'	System	14 Oct 2020 16:03:20
	System	14 Oct 2020 16:03:20

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 04:00:15

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 04:00:15

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	13 Oct 2020 16:01:24
User entered 'Day 24'	System	13 Oct 2020 16:01:24

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-15T13:22:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a1862d7f-b65a-4287-ac9f-f02406b56996'	System	15 Oct 2020 17:22:06
User entered 'No (N)'	System	15 Oct 2020 17:22:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-15T13:22:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'a1862d7f-b65a-4287-ac9f-f02406b56996' User entered '15 Oct 2020 13:22'	System	15 Oct 2020 17:22:06
	System	15 Oct 2020 17:22:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:01:24

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:01:24

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	14 Oct 2020 16:02:51
User entered 'Day 25'	System	14 Oct 2020 16:02:51

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-16T12:01:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7b540451-b060-494b-8c51-5fc085aa1974' User entered 'No (N)'	System	16 Oct 2020 16:02:47
	System	16 Oct 2020 16:02:47

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-16T12:01:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '7b540451-b060-494b-8c51-5fc085aa1974' User entered '16 Oct 2020 12:01'	System	16 Oct 2020 16:02:47
	System	16 Oct 2020 16:02:47

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:02:51

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:02:51

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	15 Oct 2020 17:21:46
User entered 'Day 26'	System	15 Oct 2020 17:21:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T08:30:14', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6f564dc3-9dbf-4b04-85ec-9cb1b66d756a' User entered 'No (N)'	System	18 Oct 2020 12:30:23
	System	18 Oct 2020 12:30:23

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T08:30:18', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '6f564dc3-9dbf-4b04-85ec-9cb1b66d756a' User entered '18 Oct 2020 08:30'	System	18 Oct 2020 12:30:23
	System	18 Oct 2020 12:30:23

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:21:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:21:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	16 Oct 2020 16:02:02
User entered 'Day 27'	System	16 Oct 2020 16:02:02

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T12:44:58', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd8fa9bd7-0b62-4f7f-8360-1bde58be08dc' User entered 'No (N)'	System	18 Oct 2020 16:45:03
	System	18 Oct 2020 16:45:03

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-18T12:45:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd8fa9bd7-0b62-4f7f-8360-1bde58be08dc' User entered '18 Oct 2020 12:45'	System	18 Oct 2020 16:45:03
	System	18 Oct 2020 16:45:03

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:02:02

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:02:02

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	18 Oct 2020 12:30:00
User entered 'Day 28'	System	18 Oct 2020 12:30:00

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T06:01:10', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b47b42b0-967d-4755-bfba-04303fcddd5d' User entered 'No (N)'	System	20 Oct 2020 10:01:17
	System	20 Oct 2020 10:01:17

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T06:01:14', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'b47b42b0-967d-4755-bfba-04303fcddd5d' User entered '20 Oct 2020 06:01'	System	20 Oct 2020 10:01:17
	System	20 Oct 2020 10:01:17

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 12:30:00

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 12:30:00

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	18 Oct 2020 16:44:49
User entered 'Day 29'	System	18 Oct 2020 16:44:49

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T12:01:51', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '08a648b8-18a7-4071-8065-678e605a3d43' User entered 'No (N)'	System	20 Oct 2020 16:02:44
	System	20 Oct 2020 16:02:44

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-20T12:01:55', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '08a648b8-18a7-4071-8065-678e605a3d43' User entered '20 Oct 2020 12:01'	System	20 Oct 2020 16:02:44
	System	20 Oct 2020 16:02:44

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 16:44:49

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 16:44:49

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	20 Oct 2020 10:00:43
User entered 'Day 30'	System	20 Oct 2020 10:00:43

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-22T00:00:19', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '82663434-8755-43b2-8666-64876e4a2382' User entered 'No (N)'	System	22 Oct 2020 04:00:26
	System	22 Oct 2020 04:00:26

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-22T00:00:24', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '82663434-8755-43b2-8666-64876e4a2382'	System	22 Oct 2020 04:00:26
User entered '22 Oct 2020 00:00'	System	22 Oct 2020 04:00:26

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 10:00:43

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 10:00:43

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	20 Oct 2020 16:02:17
User entered 'Day 31'	System	20 Oct 2020 16:02:17

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T08:48:37', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9d01573d-a962-454f-a272-9397c59448d5' User entered 'No (N)'	System	23 Oct 2020 12:48:46
	System	23 Oct 2020 12:48:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T08:48:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '9d01573d-a962-454f-a272-9397c59448d5' User entered '23 Oct 2020 08:48'	System	23 Oct 2020 12:48:46
	System	23 Oct 2020 12:48:46

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:02:17

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:02:17

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	22 Oct 2020 04:00:05
User entered 'Day 32'	System	22 Oct 2020 04:00:05

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-23T23:59:55', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ed1bdc48-5a69-4112-ae31-18c87ddcfbf'	System	24 Oct 2020 04:00:06
User entered 'No (N)'	System	24 Oct 2020 04:00:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T00:00:00', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'ed1bdc48-5a69-4112-ae31-18c87ddcfbfe' User entered '24 Oct 2020 00:00'	System	24 Oct 2020 04:00:06
	System	24 Oct 2020 04:00:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 04:00:05

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 04:00:05

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	23 Oct 2020 12:48:25
User entered 'Day 33'	System	23 Oct 2020 12:48:25

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:07:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '66f711d4-c604-48b8-83cc-2e80f336e2d6' User entered 'No (N)'	System	24 Oct 2020 17:07:53
	System	24 Oct 2020 17:07:53

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:07:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '66f711d4-c604-48b8-83cc-2e80f336e2d6' User entered '24 Oct 2020 13:07'	System	24 Oct 2020 17:07:53
	System	24 Oct 2020 17:07:53

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 12:48:25

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 12:48:25

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Oct 2020 03:59:41
User entered 'Day 34'	System	24 Oct 2020 03:59:41

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-25T12:00:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'aa004394-5560-40fc-bdaf-09e683f3a737'	System	25 Oct 2020 16:00:53
User entered 'No (N)'	System	25 Oct 2020 16:00:53

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-25T12:00:50', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'aa004394-5560-40fc-bdaf-09e683f3a737'	System	25 Oct 2020 16:00:53
User entered '25 Oct 2020 12:00'	System	25 Oct 2020 16:00:53

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:59:41

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:59:41

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Oct 2020 17:07:31
User entered 'Day 35'	System	24 Oct 2020 17:07:31

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-26T13:18:42', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '3d37eeff-616b-45d4-879a-3222c748aed6' User entered 'No (N)'	System	26 Oct 2020 17:18:47
	System	26 Oct 2020 17:18:47

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-26T13:18:46', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '3d37eeff-616b-45d4-879a-3222c748aed6' User entered '26 Oct 2020 13:18'	System	26 Oct 2020 17:18:47
	System	26 Oct 2020 17:18:47

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:07:31

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:07:31

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	25 Oct 2020 16:00:38
User entered 'Day 36'	System	25 Oct 2020 16:00:38

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-27T16:37:23', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '732d41cb-6ef0-4802-a54e-6c782fc98c3f' User entered 'No (N)'	System	27 Oct 2020 20:37:34
	System	27 Oct 2020 20:37:34

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-27T16:37:27', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '732d41cb-6ef0-4802-a54e-6c782fc98c3f' User entered '27 Oct 2020 16:37'	System	27 Oct 2020 20:37:34
	System	27 Oct 2020 20:37:34

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 16:00:38

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 16:00:38

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	26 Oct 2020 17:18:28
User entered 'Day 37'	System	26 Oct 2020 17:18:28

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-28T12:01:09', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2a23d3eb-b98d-4e44-8420-e59375b5f53c' User entered 'No (N)'	System	28 Oct 2020 16:01:49
	System	28 Oct 2020 16:01:49

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-28T12:01:14', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '2a23d3eb-b98d-4e44-8420-e59375b5f53c' User entered '28 Oct 2020 12:01'	System	28 Oct 2020 16:01:49
	System	28 Oct 2020 16:01:49

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:18:28

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:18:28

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	27 Oct 2020 20:37:11
User entered 'Day 38'	System	27 Oct 2020 20:37:11

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T08:01:17', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '93af693e-d25a-471d-8331-a7a7dbd47668' User entered 'No (N)'	System	30 Oct 2020 12:01:22
	System	30 Oct 2020 12:01:22

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T08:01:21', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '93af693e-d25a-471d-8331-a7a7dbd47668' User entered '30 Oct 2020 08:01'	System	30 Oct 2020 12:01:22
	System	30 Oct 2020 12:01:22

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 20:37:11

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 20:37:11

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	28 Oct 2020 16:01:21
User entered 'Day 39'	System	28 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T12:31:59', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'bba10162-8556-4d93-8ccb-0cb6cc6d5830' User entered 'No (N)'	System	30 Oct 2020 16:32:10
	System	30 Oct 2020 16:32:10

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-30T12:32:03', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'bba10162-8556-4d93-8ccb-0cb6cc6d5830' User entered '30 Oct 2020 12:32'	System	30 Oct 2020 16:32:10
	System	30 Oct 2020 16:32:10

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 16:01:21

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Oct 2020 12:01:06
User entered 'Day 40'	System	30 Oct 2020 12:01:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T07:48:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '12f8fc26-13b5-4122-88dc-bf671203d079' User entered 'No (N)'	System	01 Nov 2020 12:48:57
	System	01 Nov 2020 12:48:57

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T07:48:54', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '12f8fc26-13b5-4122-88dc-bf671203d079' User entered '01 Nov 2020 07:48'	System	01 Nov 2020 12:48:57
	System	01 Nov 2020 12:48:57

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 12:01:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 12:01:06

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	30 Oct 2020 16:31:50
User entered 'Day 41'	System	30 Oct 2020 16:31:50

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T12:54:30', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd2e418a9-06b6-427f-a02a-c3d9b50bf0cc' User entered 'No (N)'	System	01 Nov 2020 17:54:38
	System	01 Nov 2020 17:54:38

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-01T12:54:34', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'd2e418a9-06b6-427f-a02a-c3d9b50bf0cc' User entered '01 Nov 2020 12:54'	System	01 Nov 2020 17:54:38
	System	01 Nov 2020 17:54:38

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 16:31:50

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 16:31:50

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Nov 2020 12:48:18
User entered 'Day 42'	System	01 Nov 2020 12:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '02 Nov 2020 12:00'	System	01 Nov 2020 12:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Nov 2020 11:59'	System	01 Nov 2020 12:48:18

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	01 Nov 2020 17:54:22
User entered 'Day 43'	System	01 Nov 2020 17:54:22

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-04T00:00:36', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '015a364e-6c2c-48b8-90d7-d99b38993673' User entered 'No (N)'	System	04 Nov 2020 05:00:42
	System	04 Nov 2020 05:00:42

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-04T00:00:39', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '015a364e-6c2c-48b8-90d7-d99b38993673' User entered '04 Nov 2020 00:00'	System	04 Nov 2020 05:00:42
	System	04 Nov 2020 05:00:42

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 17:54:22

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 17:54:22

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Nov 2020 05:00:21
User entered 'Day 44'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	04 Nov 2020 05:00:21
User entered 'Day 45'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 16:08:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 05:00:21

US3222315

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 16:08:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 05:00:21

US3222315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 00:36:31

US3222315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:55:00
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 19:19:36
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DATE IS CORRECT AS ENTERED' (Site from System).	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 00:37:02
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Nov 2020 00:36:31
User entered '22 Sep 2020'	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 00:36:31

US3222315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	11 Nov 2020 00:36:31

US3222315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 00:36:31

US3222315

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:21:54

US3222315

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	22 Oct 2020 19:21:54

US3222315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 00:37:22

US3222315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '8 Oct 2020'	Albert Garcia (b) (4)	11 Nov 2020 00:37:22

US3222315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	11 Nov 2020 00:37:22

US3222315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 00:37:22

US3222315

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:22:18

US3222315

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	22 Oct 2020 19:22:18

US3222315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 00:37:55

US3222315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '13 Oct 2020'	Albert Garcia (b) (4)	11 Nov 2020 00:37:55

US3222315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	11 Nov 2020 00:37:55

US3222315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 00:37:55

US3222315

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	22 Oct 2020 19:22:29

US3222315

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	22 Oct 2020 19:22:29

US3222315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	22 Oct 2020 19:22:44

US3222315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '22 Oct 2020'	Alicia Cevera (b) (4)	22 Oct 2020 19:22:44

US3222315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Clinic (Clinic)'	Alicia Cevera (b) (4)	22 Oct 2020 19:22:44

US3222315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered 'VISIT3'	System	22 Oct 2020 19:22:44

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	Alicia Cevera (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered empty.	System	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered empty.	System	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered empty.	System	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered empty.	System	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered empty.	System	22 Oct 2020 19:23:10

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09

US3222315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09

US3222315

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:23:51

US3222315

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	Alicia Cevera (b) (4)	22 Oct 2020 19:23:51

US3222315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:24:05

US3222315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '22 Oct 2020'	Alicia Cevera (b) (4)	22 Oct 2020 19:24:05

US3222315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '08:22'	Alicia Cevera (b) (4)	22 Oct 2020 19:24:05

US3222315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '22 Oct 2020 08:22'	System	22 Oct 2020 19:24:05

US3222315

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:24:12

US3222315

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	22 Oct 2020 19:24:12

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 64'	System	24 Aug 2020 21:02:11

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:08:13', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '75e0d1cd-a3f8-47b9-8010-3ccde34e8465'	System	24 Oct 2020 17:08:50
User entered 'No (N)'	System	24 Oct 2020 17:08:50

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:08:20', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '75e0d1cd-a3f8-47b9-8010-3ccde34e8465'	System	24 Oct 2020 17:08:50
User entered 'No (N)'	System	24 Oct 2020 17:08:50

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-24T13:08:48', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '75e0d1cd-a3f8-47b9-8010-3ccde34e8465' User entered '24 Oct 2020 13:08:48'	System	24 Oct 2020 17:08:50
	System	24 Oct 2020 17:08:50

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 21:02:11

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 71'	System	24 Aug 2020 21:02:11

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-31T00:54:29', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'c86c1ad8-9de4-480f-aa63-f010e0646fa4' User entered 'No (N)'	System	31 Oct 2020 04:54:48
	System	31 Oct 2020 04:54:48

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-31T00:54:35', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'c86c1ad8-9de4-480f-aa63-f010e0646fa4'	System	31 Oct 2020 04:54:48
User entered 'No (N)'	System	31 Oct 2020 04:54:48

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-10-31T00:54:45', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: 'c86c1ad8-9de4-480f-aa63-f010e0646fa4' User entered '31 Oct 2020 00:54:45'	System	31 Oct 2020 04:54:48
	System	31 Oct 2020 04:54:48

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 21:02:11

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered 'Day 78'	System	24 Aug 2020 21:02:11

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-07T07:00:43', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1e845faf-eef4-493a-b6db-d341efcda3fb' User entered 'No (N)'	System	07 Nov 2020 12:01:06
	System	07 Nov 2020 12:01:06

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-07T07:00:53', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1e845faf-eef4-493a-b6db-d341efcda3fb'	System	07 Nov 2020 12:01:06
User entered 'No (N)'	System	07 Nov 2020 12:01:06

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-07T07:01:02', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '1e845faf-eef4-493a-b6db-d341efcda3fb' User entered '07 Nov 2020 07:01:02'	System	07 Nov 2020 12:01:06
	System	07 Nov 2020 12:01:06

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 21:02:11

US3222315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:48
Data entry locked.	System	24 Aug 2020 21:02:11
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 21:02:11

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-21T06:10:49', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0312d705-4f2a-46ea-914e-cf5d8aaae0da' User entered 'No (N)'	System	21 Nov 2020 11:11:11
	System	21 Nov 2020 11:11:11

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-21T06:10:57', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0312d705-4f2a-46ea-914e-cf5d8aaae0da' User entered 'No (N)'	System	21 Nov 2020 11:11:11

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (669183AC-6081-4B15-B5AC-4CD805D608D9)', Time: '2020-11-21T06:11:08', User OID: 'PatientReportedOutcome (US3222315)', ODM File OID: '0312d705-4f2a-46ea-914e-cf5d8aaae0da' User entered '21 Nov 2020 06:11:08'	System	21 Nov 2020 11:11:11
	System	21 Nov 2020 11:11:11

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 02:03:17

US3222315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:08:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:17
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 02:03:17

US3222315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:20:27

US3222315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered '16 Nov 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:20:27

US3222315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:20:27

US3222315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:20:27

US3222315

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 14:20:36

US3222315

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:39:09
User entered '1'	System	02 Dec 2020 14:20:36

US3222315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	heather jackson (b) (4)	23 Dec 2020 14:54:29

US3222315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '18 Dec 2020'	heather jackson (b) (4)	23 Dec 2020 14:54:29

US3222315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	23 Dec 2020 14:54:29

US3222315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	heather jackson (b) (4)	23 Dec 2020 14:54:29

US3222315

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	heather jackson (b) (4)	23 Dec 2020 14:54:34

US3222315

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User entered '1'	System	23 Dec 2020 14:54:34

US3222315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 17:48:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 17:48:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 17:48:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 20:19:15
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	21 Jan 2021 20:19:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 20:19:15
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	21 Jan 2021 20:14:32
User entered 'No (N)'	(b) (4), (b) (6)	21 Jan 2021 20:14:32

US3222315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 17:48:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 20:19:15
User entered '21 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 20:14:32

US3222315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:48:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 20:19:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	21 Jan 2021 20:14:32

US3222315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:15
User entered 'THREE ATTEMPTS MADE, LEFT VOICEMAILS, NO ANSWER OR REPLIES MADE.'	(b) (4), (b) (6)	21 Jan 2021 20:14:32

US3222315

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 16:51:05

US3222315

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User entered '1'	System	17 Feb 2021 16:51:05

US3222315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 16:53:02

US3222315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 16:53:02

US3222315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 16:53:02

US3222315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Spoke with subject, no new medications or illnesses. (b) (6)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 16:53:02

US3222315

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4)	24 Mar 2021 11:00:14

US3222315

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:46:35
User entered '1'	System	24 Mar 2021 11:00:14

US3222315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Mar 2021 11:00:31

US3222315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered '23 Mar 2021'	Diana Toney (b) (4)	24 Mar 2021 11:00:31

US3222315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	24 Mar 2021 11:00:31

US3222315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User entered 'VISIT4'	System	24 Mar 2021 11:00:31

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User entered empty.	System	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User entered empty.	System	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User entered empty.	System	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User entered empty.	System	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User entered empty.	System	31 Mar 2021 15:25:03

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46

US3222315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46

US3222315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered 'No (N)'	Diana Toney (b) (4)	24 Mar 2021 11:00:36

US3222315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:12:40
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:00:36

US3222315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Mar 2021 11:00:53

US3222315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '23 Mar 2021'	Diana Toney (b) (4)	24 Mar 2021 11:00:53

US3222315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '11:10'	Diana Toney (b) (4)	24 Mar 2021 11:00:53

US3222315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User entered '23 Mar 2021 11:10'	System	24 Mar 2021 11:00:53

US3222315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Mar 2021 11:01:09

US3222315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:46
User entered '1'	System	24 Mar 2021 11:01:09

US3222315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:09:06

US3222315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered '19 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 12:09:06

US3222315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:09:06

US3222315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '4-19-21 @ 16:14 lvm/ (b) (6)	(b) (4)	
4-20-21 @11:30 lvm / (b) (6)	(b) (4), (b) (6)	21 Apr 2021 12:09:06
4-21-21 @ 08:00 lvm/ (b) (6)'		

US3222315

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:09:16

US3222315

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 12:09:16

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:22:22

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:22:22

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Clinic (Clinic)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:22:22

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 15:22:22

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[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 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:34:00

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:34:00

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Placebo (Placebo)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:11:57
User entered 'Placebo (Placebo)'	douglas winter (b) (4)	12 Jan 2021 15:22:44
	(b) (4)	

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:11:57
User entered 'Placebo (Placebo)'	douglas winter (b) (4)	12 Jan 2021 15:22:44
	(b) (4)	

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered '1'	System	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:08:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered '1'	System	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered empty.	System	12 Jan 2021 15:25:37
DataPoint set to visible.	System	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered empty.	System	12 Jan 2021 15:25:37
DataPoint set to visible.	System	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User accepted default value 'Pre-Dose (PREDOSE)'	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '09:36'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered '12 Jan 2021 09:36'	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '36.7' C	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Oral (Oral)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '50'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'bpm'	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '18'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'breaths/min'	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '153'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'mmHg'	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '82'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'mmHg'	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:08:31

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered empty.	System	12 Jan 2021 15:25:37
DataPoint set to visible.	System	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User accepted default value 'Post-Dose (POSTDOSE)'	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 20:24:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 20:24:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:24:29
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 15:25:37
User entered empty.	douglas winter (b) (4)	12 Jan 2021 15:25:37
	(b) (4)	

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:29
User entered empty.	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '10:56' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:29
User entered empty.	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered '12 Jan 2021 10:56'	System	08 Feb 2021 20:24:29
User entered empty.	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '36.7' C reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:29
User entered empty.	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:29
User entered empty.	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '54' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:29
User entered empty.	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'bpm'	System	08 Feb 2021 20:24:29
User entered empty.	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '18' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:29
User entered empty.	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'breaths/min'	System	08 Feb 2021 20:24:29
User entered empty.	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '160' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:29
User entered empty.	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'mmHg'	System	08 Feb 2021 20:24:29
User entered empty.	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '80' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:24:29
User entered empty.	douglas winter (b) (4) (b) (4)	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'mmHg'	System	08 Feb 2021 20:24:29
User entered empty.	System	12 Jan 2021 15:25:37

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:26:03

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:26:03

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

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)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'mRNA-1273'	System	12 Jan 2021 15:30:49
DataPoint set to visible.	System	12 Jan 2021 15:22:44

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '10:26'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered '12 Jan 2021 10:26'	System	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Right Arm (RIGHT ARM)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'ONCE'	System	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 15:30:49

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	12 Jan 2021 15:26:27

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:26:27

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '09:26'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:26:27

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered '12 Jan 2021 09:26'	System	12 Jan 2021 15:26:27

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:29:41

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:08:31

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:29:41

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:08:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '09:30'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:29:41

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:08:31

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered '12 Jan 2021 09:30'	System	12 Jan 2021 15:29:41

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	12 Jan 2021 15:31:09

US3222315

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:41:57
User entered '1'	System	12 Jan 2021 15:31:09

US3222315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:47:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	17 Mar 2021 17:49:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 17:49:10
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 20:23:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 20:23:13
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	21 Jan 2021 20:23:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 20:23:13
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 18:09:42
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:09:42

US3222315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:47:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 20:23:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:09:42

US3222315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:47:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 20:23:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:09:42

US3222315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:47:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'THREE ATTEMPTS MADE, LEFT VOICEMAILS, NO ANSWER OR REPLIES MADE.' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 20:23:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:09:42

US3222315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:47:52
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:56:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:24:58

US3222315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:47:52
User entered '1'	System	08 Feb 2021 20:24:58

US3222315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:47:52
User entered '1'	System	08 Feb 2021 20:24:58
DataPoint set to visible.	System	08 Feb 2021 20:24:58

US3222315

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:30:10

US3222315

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:30:10

US3222315

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:30:10

US3222315

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'OLD29'	System	08 Feb 2021 20:30:10

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '11:53'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered '08 Feb 2021 11:53'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '63'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'bpm'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'breaths/min'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '120'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'mmHg'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '72'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'mmHg'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '13:47'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered '08 Feb 2021 13:47'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '58'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'bpm'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'breaths/min'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '135'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'mmHg'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '82'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:08:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'mmHg'	System	08 Feb 2021 20:32:26

US3222315

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:30:20

US3222315

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:30:20

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

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)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'mRNA-1273'	System	08 Feb 2021 20:25:24
DataPoint set to visible.	System	08 Feb 2021 20:24:58

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '13:07'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered '08 Feb 2021 13:07'	System	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'ONCE'	System	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:08:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 20:25:24

US3222315

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:29:57

US3222315

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:50
User entered '1'	System	08 Feb 2021 20:29:57

US3222315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Mar 2021 11:01:47

US3222315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '17 Feb 2021'	Diana Toney (b) (4)	24 Mar 2021 11:01:47

US3222315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Contact Made (CONTACT MADE)'	Diana Toney (b) (4)	24 Mar 2021 11:01:47

US3222315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:08:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:01:47

US3222315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Mar 2021 11:01:52

US3222315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:08:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:59
User entered '1'	System	24 Mar 2021 11:01:52

US3222315

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4)	24 Mar 2021 11:02:09

US3222315

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'confirmed oow 1 day' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 08:45:29
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'confirmed oow 1 day' (Site from System).	Diana Toney (b) (4)	24 Mar 2021 11:05:08
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
User entered '23 Mar 2021'	System	24 Mar 2021 11:02:09
	Diana Toney (b) (4)	24 Mar 2021 11:02:09
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	24 Mar 2021 11:02:09

US3222315

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:08:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User entered 'OLD57'	System	24 Mar 2021 11:02:09

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Diana Toney (b) (4)	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User entered empty.	System	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User entered empty.	System	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User entered empty.	System	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User entered empty.	System	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User entered empty.	System	24 Mar 2021 11:06:02

US3222315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:08:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Diana Toney (b) (4)	24 Mar 2021 11:06:09

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:08:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	Diana Toney (b) (4)	24 Mar 2021 11:06:09

US3222315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Mar 2021 11:10:49

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '23 Mar 2021'	Diana Toney (b) (4)	24 Mar 2021 11:10:49

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '11:10'	Diana Toney (b) (4)	24 Mar 2021 11:10:49

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:08:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:09:17
User entered '23 Mar 2021 11:10'	System	24 Mar 2021 11:10:49

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:08:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:12
User closed query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Muscle aches all over persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 17:17:46
Query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Muscle aches all over persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'DONE' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:37:41
User opened query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Muscle aches all over persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:29:49
User closed query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Joint aches in several joints and Muscle aches all over persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:29:49

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:08:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Joint aches in several joints and Muscle aches all over persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'symptoms recorded in AE eCRF. Source documents completed for AEs' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 18:29:46
User opened query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 1 Record, symptom of Joint aches in several joints and Muscle aches all over persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 10:07:02
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:47:02
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:40:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:49:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:40
User entered	System	24 Sep 2020 01:34:36
'USA-US104-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	24 Sep 2020 01:34:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'PV Query: This is an elective surgery- pre planned. Thus it is not emergent and should not be reported as SAE. Further, causes for surgery should be recorded as SAE- not the surgery. Please ensure that only emergent events are captured per protocol.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:08:25
User closed query 'PV Query: The event term should be the indication for the procedure, not the procedure itself. Please report the indication for the right hip arthroplasty and consider updating the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 16:07:31
Query 'PV Query: This is an elective surgery- pre planned. Thus it is not emergent and should not be reported as SAE. Further, causes for surgery should be recorded as SAE- not the surgery. Please ensure that only emergent events are captured per protocol.' answered with 'Per PI and protocol this is an SAE' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 13:42:10
Query 'PV Query: The event term should be the indication for the procedure, not the procedure itself. Please report the indication for the right hip arthroplasty and consider updating the event term accordingly.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 13:41:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 13:36:49
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 13:36:49
Data point term sent to Coder	System	02 Dec 2020 13:34:45
Coding entries removed.	gail lavine (b) (4) (b) (4)	02 Dec 2020 13:34:44
User entered 'osteoarthritis right hip' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 13:34:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: This is an elective surgery- pre planned. Thus it is not emergent and should not be reported as SAE. Further, causes for surgery should be recorded as SAE- not the surgery. Please ensure that only emergent events are captured per protocol.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:32:50
User opened query 'PV Query: The event term should be the indication for the procedure, not the procedure itself. Please report the indication for the right hip arthroplasty and consider updating the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:32:20
User closed query 'PV Query: The event term should be the indication for the procedure. Please report the indication for the left hip arthroplasty and consider updating the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 12:51:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip arthroplasty - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 00:50:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 00:50:43
Data point term sent to Coder	System	11 Nov 2020 00:50:09
User entered 'ARTHROPLASTY - RIGHT HIP' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 00:49:15
Data point term sent to Coder	System	11 Nov 2020 00:43:03
Query 'PV Query: The event term should be the indication for the procedure. Please report the indication for the left hip arthroplasty and consider updating the event term accordingly.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	11 Nov 2020 00:42:14
DataPoint Un-verified.	Albert Garcia (b) (4)	11 Nov 2020 00:42:02
Coding entries removed.	Albert Garcia (b) (4)	11 Nov 2020 00:42:02
User entered 'ARTHROPLASTY - LEFT HIP' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 00:42:02
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:49:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The event term should be the indication for the procedure. Please report the indication for the left hip arthroplasty and consider updating the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:05:14
Query 'IQVIA medical query: The event term should be the indication for the procedure. Please report the indication for the left hip arthroplasty and consider updating the event term accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:04:53
User opened query 'IQVIA medical query: The event term should be the indication for the procedure. Please report the indication for the left hip arthroplasty and consider updating the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:04:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 19:45:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 19:45:40
Data point term sent to Coder	System	23 Sep 2020 19:44:00
User entered 'LEFT HIP ARTHROPLASTY'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:49:52
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 05:54:21
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 00:43:59
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 00:42:35
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 23:21:56
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:26
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:28
User entered '9 Sep 2020'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

US3222315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:51:41
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	23 Sep 2020 19:43:35
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	23 Sep 2020 19:43:35
	(b) (4)	
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	23 Sep 2020 19:43:14
User entered '08:00'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:43:35
User entered '9 Sep 2020 08:00'	System	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 01:21:44
DataPoint Un-verified.	Albert Garcia (b) (4)	11 Nov 2020 01:21:44
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 01:21:44
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 01:21:29
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:51:43
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Sep 2020 19:44:24
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered '10 Sep 2020' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 13:34:44
	(b) (4)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	11 Nov 2020 01:21:29
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 01:21:29
DataPoint Un-verified.	Albert Garcia (b) (4)	11 Nov 2020 01:21:29
	(b) (4)	
User entered '09 Nov 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 01:21:29
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	11 Nov 2020 01:02:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:51:46
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Sep 2020 19:44:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Sep 2020 19:44:24
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	23 Sep 2020 19:44:24
	(b) (4)	
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Sep 2020 19:43:14
User entered '10 Sep 2020'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:51:49
User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	23 Sep 2020 19:45:18
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	23 Sep 2020 19:45:18
	(b) (4)	
User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	23 Sep 2020 19:44:24
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	23 Sep 2020 19:44:24
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	23 Sep 2020 19:43:14
User entered '10:00'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: The event end date has been reported, please consider updating the final event outcome.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:33:36
User opened query 'PV Query: The event end date has been reported, please consider updating the final event outcome.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:03:18
User entered empty.	System	23 Sep 2020 19:44:24
User entered '10 Sep 2020 10:00'	System	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:54
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

US3222315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:52:03
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Sep 2020 19:45:18
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Sep 2020 19:43:14
User entered 'Yes (Y)'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:52:06
User entered '0'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

US3222315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:52:08
User entered '0'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:52:11
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Sep 2020 19:45:18
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		23 Sep 2020 19:45:18
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	23 Sep 2020 19:45:18
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Sep 2020 19:43:14
User entered '0'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:13
User entered '9 Sep 2020'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

US3222315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:15
User entered '10 Sep 2020'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:18
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:21
User entered empty.	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:24
User entered '0'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:26
User entered '0'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:52:29
User entered '0'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:39
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:43
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:53:36
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:53:39
User entered '0'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 08:57:38
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'CONMEDS ARE ENTERED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	17 Mar 2021 17:28:23
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:42:04
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 12:51:38
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'CONMEDS HAVE BEEN LISTED ON CONMED PAGE ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:02:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:53:42

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:03:41
User entered '1'	douglas winter (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:53:45
User entered '0'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:39:27
User closed query 'Per source, the outcome is recovered/resolved. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:39:26
Query 'Per source, the outcome is recovered/resolved. Please verify and update accordingly.' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4)	11 Nov 2020 01:02:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 01:02:11
User opened query 'Per source, the outcome is recovered/resolved. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:54:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	douglas winter (b) (4)	23 Sep 2020 19:43:14
	(b) (4)	

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:55:38
User entered empty.	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'PV Query: Thank you for updating the concomitant procedure section with test completed. Please update the narrative to reflect test results. Please include units and reference ranges if applicable. When information becomes available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:20:49
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 13:20:45
Query 'PV Query: Thank you for updating the concomitant procedure section with test completed. Please update the narrative to reflect test results. Please include units and reference ranges if applicable. When information becomes available. ' answered with 'updated narrative' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 17:26:05
User entered 'ELECTIVE RIGHT HIP ARTHROPLASTY ADMITTED TIME PER PATIENT 08:00 AM 09/SEP/2020 & DISCHARGE TIME PER PATIENT 10:00 AM ON 10/SEP/2020. REQUESTING MEDICAL RECORDS. MEDICAL RECORDS RECEIVED , ALL TEST RESULTS ARE WITHIN NORMAL RANGE.' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 17:25:46
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary not available , operative report sent.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 17:10:52
User opened query 'PV Query: Thank you for updating the concomitant procedure section with test completed. Please update the narrative to reflect test results. Please include units and reference ranges if applicable. When information becomes available. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:35:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for updating the event term to right hip arthroplasty. Please update the narrative section as it reflects left hip arthroplasty.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 16:07:50
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)	03 Dec 2020 16:07:25
Query 'PV Query: Thank you for updating the event term to right hip arthroplasty. Please update the narrative section as it reflects left hip arthroplasty.' answered with 'updated' (Site from Safety).	gail lavine (b) (4)	02 Dec 2020 14:02:40
DataPoint Un-verified.	gail lavine (b) (4)	02 Dec 2020 14:02:20
User entered 'ELECTIVE right HIP ARTHROPLASTY ADMITTED TIME PER PATIENT 08:00 AM 09/SEP/2020 & DISCHARGE TIME PER PATIENT 10:00 AM ON 10/SEP/2020. REQUESTING MEDICAL RECORDS' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 14:02:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'tests added to con procedures ' (Site from Safety).	gail lavine (b) (4)	02 Dec 2020 14:01:03
User opened query 'PV Query: Thank you for updating the event term to right hip arthroplasty. Please update the narrative section as it reflects left hip arthroplasty.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:32:33
User closed query 'PV Query: Per paper SAE form, osteoarthritis is listed as relevant medical history. If correct, please add to EDC.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 12:51:43
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 12:51:41
Query 'PV Query: Per paper SAE form, osteoarthritis is listed as relevant medical history. If correct, please add to EDC.' answered with 'OSTEOARTHRITIS HAS BEEN ADDED TO THE MH PER RECORDS' (Site from Safety).	Albert Garcia (b) (4)	11 Nov 2020 01:22:26

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'CONMEDS HAVE BEEN UPATED' (Site from Safety). DataPoint Verified.	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:03:09
	(b) (4), (b) (6)	04 Nov 2020 16:55:51
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:05:25
User opened query 'PV Query: Per paper SAE form, osteoarthritis is listed as relevant medical history. If correct, please add to EDC.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:04:20
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:04:01
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)	02 Oct 2020 17:03:51
User entered 'ELECTIVE LEFT HIP ARTHROPLASTY ADMITTED TIME PER PATIENT 08:00 AM 09/SEP/2020 & DISCHARGE TIME PER PATIENT 10:00 AM ON 10/SEP/2020. REQUESTING MEDICAL RECORDS'	douglas winter (b) (4) (b) (4)	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:08:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 19:43:14

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User closed query 'Per CDM: Please review and update AE term to reflect if the JOINT ACHES is Generalized or found on a specific body location. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 00:58:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4)	26 Apr 2021 12:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Apr 2021 12:39:49
Data point term sent to Coder	System	26 Apr 2021 12:38:29
Query 'Per CDM: Please review and update AE term to reflect if the JOINT ACHES is Generalized or found on a specific body location. Thank you' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:38:21
Coding entries removed.	(b) (4), (b) (6)	26 Apr 2021 12:38:11
User entered 'JOINT ACHES (GENERALIZED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 12:38:11
User opened query 'Per CDM: Please review and update AE term to reflect if the JOINT ACHES is Generalized or found on a specific body location. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:27:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:56:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:56:40
Data point term sent to Coder	System	21 Apr 2021 18:27:39
User entered 'joint aches'	(b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	21 Apr 2021 18:27:49
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	21 Apr 2021 18:27:49
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:49
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	21 Apr 2021 18:27:29
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	21 Apr 2021 18:27:29
User entered '26 Apr 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User entered empty.	System	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 18:27:29
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User entered empty.	System	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
User entered '1' reason for change: Data Entry Error	System	21 Apr 2021 18:27:29
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 18:26:50
User entered '0'	System	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:27:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	21 Apr 2021 18:27:29
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User entered '0'	System	21 Apr 2021 18:27:29

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01
User entered '0'	System	21 Apr 2021 18:26:50

US3222315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:08:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:01

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:57:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:57:15
Data point term sent to Coder	System	21 Apr 2021 18:29:41
User entered 'headache'	(b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Apr 2021 18:28:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 18:28:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 18:28:52
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User entered empty.	System	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User entered empty.	System	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User entered '0'	System	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03
User entered '0'	System	21 Apr 2021 18:28:52

US3222315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:08:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:03

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 12:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 12:39:49
Data point term sent to Coder	System	26 Apr 2021 12:38:29
User entered 'MUSCLE ACHES'	(b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User entered empty.	System	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User entered empty.	System	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User entered '0'	System	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06
User entered '0'	System	26 Apr 2021 12:37:30

US3222315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:08:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:08:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:12
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:17
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:02:54

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 14:25:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 14:25:33
Data point term sent to Coder Coding entries removed.	System	10 Nov 2020 14:24:55
	Jennifer Dittman (b) (4)	10 Nov 2020 14:24:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:09:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 19:08:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 19:08:21
Data point term sent to Coder	System	10 Oct 2020 19:07:30
User entered 'TYLENOL'	Alicia Cevera (b) (4)	10 Oct 2020 19:07:23
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	10 Oct 2020 19:07:23
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per CDM: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:42:01
DataPoint Un-verified.	Jennifer Dittman (b) (4)	10 Nov 2020 14:24:47
	(b) (4)	
User entered 'DEGENERATIVE OSTEOARTHRITIS JOINT DISEASE' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	10 Nov 2020 14:24:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:09:15
User opened query 'Per CDM: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 15:33:27
User entered 'OSTEOARTHRITIS PAIN'	Alicia Cevera (b) (4)	10 Oct 2020 19:07:23
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:20
User entered '650'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:23
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:25
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:28
User entered 'as needed (PRN)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:30
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	10 Oct 2020 19:07:23
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:32
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:35
User entered 'UN UNK 2008'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:38
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:09:41
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Oct 2020 19:07:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Oct 2020 19:07:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Alicia Cevera (b) (4)	10 Oct 2020 19:07:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Oct 2020 19:07:23
User entered empty.	Alicia Cevera (b) (4)	10 Oct 2020 19:07:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:43
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 19:07:23

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:09:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Oct 2020 05:18:18
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Oct 2020 05:18:18
	(b) (4)	
Data point term sent to Coder	System	10 Oct 2020 19:15:34
User entered 'PARAXOTINE'	Alicia Cevera (b) (4)	10 Oct 2020 19:15:26
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	10 Oct 2020 19:15:26
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 12:51:50
Query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'added depression to MH' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:30:04
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:11:19
User entered 'DEPRESSION'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:14:09
User entered '20'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:17:51
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:17:53
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'once daily (QD)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:17:58
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	10 Oct 2020 19:15:26
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:18:00
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:35:55
User closed query 'Per source, medication started in 2013. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:35:54
Query 'Per source, medication started in 2013. Please verify and update accordingly.' answered with 'UPDATED' (Site from CRA).	Jennifer Dittman (b) (4)	10 Nov 2020 14:23:01
	(b) (4)	
User entered 'UN UNK 2013' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	10 Nov 2020 14:22:56
	(b) (4)	
User opened query 'Per source, medication started in 2013. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:18:47
User entered empty.	Alicia Cevera (b) (4)	10 Oct 2020 19:15:26
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:36:03
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	10 Nov 2020 14:23:20
User entered '0' reason for change: Per Query Resolution	Jennifer Dittman (b) (4)	10 Nov 2020 14:23:20
	(b) (4)	
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	10 Nov 2020 14:22:56
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 19:15:26
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:18:53
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:18:57
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:15:26

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:19:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE/HCTZ - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Oct 2020 19:18:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Oct 2020 19:18:23
	(b) (4)	
Data point term sent to Coder	System	10 Oct 2020 19:17:35
User entered 'TRIAMTERENE/HCTZ'	Alicia Cevera (b) (4)	10 Oct 2020 19:17:05
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	10 Oct 2020 19:17:05
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:06
User entered 'HYPERTENSION'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:09
User entered '37.5/25'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:11
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:13
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'once daily (QD)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:16
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	10 Oct 2020 19:17:05
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:19
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:21
User entered 'UN UNK 2014'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:23
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:26
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:28
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:17:05

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 12:01:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 12:01:48
Data point term sent to Coder Coding entries removed.	System gail lavine (b) (4)	02 Dec 2020 14:35:37 02 Dec 2020 14:35:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:19:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:19:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:19:18
Data point term sent to Coder User entered 'TRAMADOL'	System Alicia Cevera (b) (4)	10 Oct 2020 19:19:35 10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	10 Oct 2020 19:19:13
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. If this is related to recorded AE of Arthroplasty of the Right Hip, please update indication so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:07:37
Query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. If this is related to recorded AE of Arthroplasty of the Right Hip, please update indication so there is an appropriate match. ' answered with 'updated' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:35:24
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:35:13
User entered 'right hip surgical pain secondary to Osteoarthritis' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:35:13
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. If this is related to recorded AE of Arthroplasty of the Right Hip, please update indication so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:19:56
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:19:48
User entered 'POST OPERATIVE PAIN'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:51
User entered '50'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:53
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:55
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:57
User entered 'four times daily (QID)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:19:59
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	10 Oct 2020 19:19:13
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:20:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered '11 Sep 2020'	Alicia Cevera (b) (4)	10 Oct 2020 19:19:13
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:21:39
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 19:19:13
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:24:23
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:19:13

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:24:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN HEMIHYDRATE, PRODUCTSYNONYM: LEVONOX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Oct 2020 05:15:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Oct 2020 05:15:17
Data point term sent to Coder	System	10 Oct 2020 19:22:38
User entered 'LEVONOX'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:24:34
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:24:30
User entered 'POST OPERATIVE ANTI COAGULANT'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:24:37
User entered '40'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:24:39
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:26:46
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'once daily (QD)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:26:44
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:26:24
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:26:51
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered '09 Sep 2020'	Alicia Cevera (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:26:58
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 19:22:12
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:01
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:22:12

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Dec 2020 14:38:04
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 14:38:04
Data point term sent to Coder Coding entries removed.	System gail lavine (b) (4)	02 Dec 2020 14:37:40 02 Dec 2020 14:37:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 19:25:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 19:25:24
Data point term sent to Coder User entered 'ELIQUIS'	System Alicia Cevera (b) (4)	10 Oct 2020 19:24:39 10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:09
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:07:52
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:37:15
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:37:07
User entered 'right arthroplasty secondary to right hip osteoarthritis' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:37:07
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:22:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:27:11
User entered 'POST OPERATIVE ANTI COAGULANT'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:13
User entered '2.5'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:15
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:17
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:19
User entered 'once daily (QD)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:21
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	10 Oct 2020 19:24:03
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:23
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per source, start date is 12Sep20. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:36:20
Query 'Per source, start date is 12Sep20. Please verify and update accordingly.' answered with 'UPDATED' (Site from CRA).	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:25:16
User entered '12 Sep 2020' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:25:09
User opened query 'Per source, start date is 12Sep20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:28:03
User entered '11 Sep 2020'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:28:06
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 19:24:03
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:28:08
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:24:03

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Apr 2021 16:55:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Apr 2021 16:55:48
Data point term sent to Coder Coding entries removed.	System	16 Apr 2021 16:54:36
	Amber Vasquez (b) (4)	16 Apr 2021 16:53:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Mar 2021 19:03:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Mar 2021 19:03:29
Data point term sent to Coder Coding entries removed.	System	26 Mar 2021 19:02:54
	Diana Toney (b) (4)	26 Mar 2021 19:02:33

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 14:28:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 14:28:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 14:12:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 14:12:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	17 Mar 2021 16:30:11 17 Mar 2021 16:29:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:34:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:34:45
Data point term sent to Coder Coding entries removed.	System gail lavine (b) (4) (b) (4)	02 Dec 2020 14:38:43 02 Dec 2020 14:38:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 14:26:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 14:26:32
Data point term sent to Coder Coding entries removed.	System Jennifer Dittman (b) (4)	10 Nov 2020 14:25:56 10 Nov 2020 14:25:45
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:28:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:19:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:19:19
Data point term sent to Coder User entered 'ZOFRAN'	System Alicia Cevera (b) (4)	10 Oct 2020 19:29:42 10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per CDM: Prophylaxis is "NO", however; indication recorded may indicate medication was given as a prophylaxis. Please review/update as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Prophylaxis is "NO", however; indication recorded may indicate medication was given as a prophylaxis. Please review/update as appropriate. ' answered with 'changed not prophylaxis' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 12:00:48
User opened query 'Per CDM: Prophylaxis is "NO", however; indication recorded may indicate medication was given as a prophylaxis. Please review/update as appropriate. ' (Site from DM).	Diana Toney (b) (4)	26 Mar 2021 19:03:11
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 09:59:05
	Alicia Cevera (b) (4)	10 Oct 2020 19:29:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per CDM: Please ensure that there is no corresponding Medical History/AE record that reconciles with this updated indication, Please review and update, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:06:35
Query 'Per CDM: Please ensure that there is no corresponding Medical History/AE record that reconciles with this updated indication, Please review and update, else clarify.' answered with 'This was taken for prophylaxis post surgery, no Medical history or AE to be added. ' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	16 Apr 2021 17:09:04
User entered 'NAUSEA prophylaxis' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	16 Apr 2021 16:53:53
User opened query 'Per CDM: Please ensure that there is no corresponding Medical History/AE record that reconciles with this updated indication, Please review and update, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 12:06:25
User entered 'NAUSEA' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	26 Mar 2021 19:02:33
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:59:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated term for nausea ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:30:36
User entered 'prophylaxis for nausea.' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:29:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 13:59:43
User closed query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 07:20:20
Query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:38:30
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:38:19
User entered 'right hip arthroplasty post surgical nausea' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:38:19
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:25:33
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:36:37
User closed query 'Per source, indication is nausea. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:36:34
Query 'Per source, indication is nausea. Please verify and update accordingly.' answered with 'UPDATED' (Site from CRA).	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:26:12
User entered 'NAUSEA' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:25:45
User opened query 'Per source, indication is nausea. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:29:28

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'ANTIEMETIC'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:29:35
User entered '4'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:29:36
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:29:39
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:36:49
User closed query 'Per source, frequency is QD. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:36:46
Query 'Per source, frequency is QD. Please verify and update accordingly. ' answered with 'UPDATED' (Site from CRA).	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:26:26
User entered 'once daily (QD)' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:26:20
User opened query 'Per source, frequency is QD. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:30:14
User entered 'as needed (PRN)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:30:18
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:30:24
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Un-verified.	(b) (4)	
	Amber Vasquez (b) (4)	16 Apr 2021 17:07:53
	(b) (4)	
User entered '09 Sep 2020' reason for change: Data Entry Error	Amber Vasquez (b) (4)	16 Apr 2021 17:07:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:30:27
User entered '12 Sep 2020'	Alicia Cevera (b) (4)	10 Oct 2020 19:29:01
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:30:29
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	16 Apr 2021 17:07:53
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Apr 2021 17:07:53
	(b) (4)	
	Alicia Cevera (b) (4)	10 Oct 2020 19:29:01
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Un-verified.	(b) (4)	
	Amber Vasquez (b) (4)	16 Apr 2021 17:07:53
	(b) (4)	
User entered '10 Sep 2020' reason for change: Data Entry Error	Amber Vasquez (b) (4)	16 Apr 2021 17:07:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:30:33
User entered empty.	Alicia Cevera (b) (4)	10 Oct 2020 19:29:01
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User entered '1'	System	10 Nov 2020 14:26:20
User entered empty.	System	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User entered '1'	System	10 Nov 2020 14:26:20
User entered empty.	System	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:21
User entered '804 (804)'	System	10 Nov 2020 14:26:20
User entered empty.	System	10 Oct 2020 19:29:01

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:54:43
Data point term sent to Coder	System	02 Dec 2020 14:40:44
Coding entries removed.	gail lavine (b) (4)	02 Dec 2020 14:40:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:18:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 05:18:18
Data point term sent to Coder	System	10 Oct 2020 19:33:47
User entered 'PERCOCET'	Alicia Cevera (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	10 Oct 2020 19:32:49
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. If this is related to recorded AE of Arthroplasty of the Right Hip, please update indication so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 07:21:51
Query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. If this is related to recorded AE of Arthroplasty of the Right Hip, please update indication so there is an appropriate match. ' answered with 'updated' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:40:37
User entered 'right hip arthroplasty pain secondary to right hip osteoarthritis' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 14:40:26
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. If this is related to recorded AE of Arthroplasty of the Right Hip, please update indication so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:27:53
User entered 'POST OPERATIVE PAIN CONTROL'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Dec 2020 02:25:32
User closed query 'Re-query: 1 tablet is not appropriate for entry. Please reconcile with actual dose per administration as it is noted as 5/325 in source' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:25:30
Query 'Re-query: 1 tablet is not appropriate for entry. Please reconcile with actual dose per administration as it is noted as 5/325 in source' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4)	16 Nov 2020 20:14:20
	(b) (4)	
User entered '5/325' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Nov 2020 20:12:35
	(b) (4)	
User opened query 'Re-query: 1 tablet is not appropriate for entry. Please reconcile with actual dose per administration as it is noted as 5/325 in source' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:37:50
User closed query 'Per source dose is listed as 5/325. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:37:50
Query 'Per source dose is listed as 5/325. Please verify and update accordingly.' answered with '5.325 QID IS CORRECT' (Site from CRA).	Albert Garcia (b) (4)	10 Nov 2020 20:49:59
	(b) (4)	
User opened query 'Per source dose is listed as 5/325. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:35:12
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 19:32:49
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	16 Nov 2020 20:12:35
	(b) (4)	
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4)	10 Oct 2020 19:32:49
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:35:59
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per source, medication was taken PRN. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:38:07
Query 'Per source, medication was taken PRN. Please verify and update accordingly.' answered with 'QID IS CORRET' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:50:07
User opened query 'Per source, medication was taken PRN. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:35:53
User entered 'four times daily (QID)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:02
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	10 Oct 2020 19:32:49
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:09
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:13
User entered '12 Sep 2020'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:14
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 19:32:49
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:17
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:32:49

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 07:12:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:12:22
Data point term sent to Coder Coding entries removed.	System Diana Toney (b) (4) (b) (4)	26 Mar 2021 19:07:06 26 Mar 2021 19:06:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:13:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:13:00
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6) (b) (4)	17 Mar 2021 16:40:22 17 Mar 2021 16:39:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:29:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:29:45
Data point term sent to Coder	System	11 Nov 2020 00:50:09

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Nov 2020 00:45:05
Coding entries removed.	Albert Garcia (b) (4)	11 Nov 2020 00:44:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:36:47
User coded data point as ATC:	Coder Import (b) (4)	10 Oct 2020 19:34:22
MUSCULO-SKELETAL SYSTEM, ATC:	(b) (4)	
ANTIINFLAMMATORY AND ANTIRHEUMATIC		
PRODUCTS, ATC: ANTIINFLAMMATORY AND		
ANTIRHEUMATIC PRODUCTS,		
NON-STERIODS, ATC: COXIBS, PRODUCT:		
CELECOXIB, PRODUCTSYNONYM: CELEBREX		
- version WHODrug-Global-B3\202003.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Oct 2020 19:34:22
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	10 Oct 2020 19:33:50
User entered 'CELEBREX'	Alicia Cevera (b) (4)	10 Oct 2020 19:33:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	10 Oct 2020 19:33:47
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per CDM: Please review and confirm if this pertains to 'OSTEOARTHRITIS RIGHT HIP' (# 1) in the AE eCRF? If yes, please update as appropriate to maintain consistency among eCRF pages. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:07:03
Query 'Per CDM: Please review and confirm if this pertains to 'OSTEOARTHRITIS RIGHT HIP' (# 1) in the AE eCRF? If yes, please update as appropriate to maintain consistency among eCRF pages. ' answered with 'updated on both edc and med hx' (Site from DM).	Diana Toney (b) (4) (b) (4)	26 Mar 2021 19:07:52
User entered 'OSTEOARTHRITIS RT HIP' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	26 Mar 2021 19:06:55
User opened query 'Per CDM: Please review and confirm if this pertains to 'OSTEOARTHRITIS RIGHT HIP' (# 1) in the AE eCRF? If yes, please update as appropriate to maintain consistency among eCRF pages. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 10:03:43
User closed query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 10:03:43
Query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:40:00
User entered 'OSTEOARTHRITIS - HIPS' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:39:48
User opened query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 13:57:51
User closed query 'Per CDM: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 12:33:57
User entered 'OSTEOARTHRITIS PAIN - RIGHT HIP' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 00:49:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	11 Nov 2020 00:45:00
User entered 'OSTEOARTHRITIS PAIN - LEFT HIP' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 00:44:56
User opened query 'Per CDM: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 15:34:57
User entered 'OSTEOARTHRITIS PAIN'	Alicia Cevera (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:05
User entered '200'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:08
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:10
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:12
User entered 'once daily (QD)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:14
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:16
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:18
User entered '12 Sep 2020'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:21
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 19:33:47
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:23
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:33:47

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:37:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: AZO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Oct 2020 05:12:16
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Oct 2020 05:12:16
	(b) (4)	
Data point term sent to Coder	System	10 Oct 2020 19:35:50
User entered 'AZO'	Alicia Cevera (b) (4)	10 Oct 2020 19:34:58
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 19:34:58
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:36
User entered 'URINARY TRACT PAIN'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:38:27
User closed query 'Per source, dose is 195 mg. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:38:24
Query 'Per source, dose is 195 mg. Please verify and update accordingly.' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4)	10 Nov 2020 20:52:41
	(b) (4)	
User entered '195' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 20:52:33
	(b) (4)	
User opened query 'Per source, dose is 195 mg. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:38:13
User entered '2'	Alicia Cevera (b) (4)	10 Oct 2020 19:34:58
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:38:28
User entered 'mg (mg)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:52:33
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:16
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'once daily (QD)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:23
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:26
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:29
User entered '12 Sep 2020'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:31
User entered '0'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 19:34:58
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:35
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:34:58

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:38:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Oct 2020 05:09:16
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Oct 2020 05:09:16
	(b) (4)	
Data point term sent to Coder	System	10 Oct 2020 19:36:51
User entered 'GABAPENTIN'	Alicia Cevera (b) (4)	10 Oct 2020 19:35:56
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	10 Oct 2020 19:35:56
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'FIBROMYALGIA PAIN'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:07
User entered '300'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:09
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:12
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:14
User entered 'three times daily (TID)'	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:18
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	10 Oct 2020 19:35:56
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:20
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	10 Oct 2020 19:35:56
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:40:30
User entered '1'	Alicia Cevera (b) (4)	10 Oct 2020 19:35:56
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	10 Oct 2020 19:35:56
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:32
User entered empty.	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 19:35:56

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:52:37
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)	22 Oct 2020 19:26:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:26:50
Data point term sent to Coder	System	22 Oct 2020 19:25:56
User entered 'INFLUENZA VACCINE'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:52:43
User entered 'SEASONAL INFLUENZA'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Please enter dose.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:38:45
Query 'Please enter dose.' answered with 'UPDATE' (Site from CRA).	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:18:40
User entered '0.5' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:17:28
User opened query 'Please enter dose.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:52:57
User entered '1'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	10 Nov 2020 20:54:26
User entered 'Other (OTHER)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:54:26
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	10 Nov 2020 14:17:28
User entered 'mL (mL)' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:17:28
User entered 'Other (OTHER)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:00
User entered 'INJECTION'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:03
User entered 'once (ONCE)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:06
User entered empty.	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:08
User entered 'Intramuscular (INTRAMUSCULAR)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:10
User entered empty.	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:15
User entered '21 Oct 2020'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:16
User entered '0'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:19
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:22
User entered '21 Oct 2020'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:53:23
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User entered empty.	System	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User entered empty.	System	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:26
User entered empty.	System	22 Oct 2020 19:25:45

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:50:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:28:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:28:41
Data point term sent to Coder	System	22 Oct 2020 19:27:58
User entered 'SHINGLES VACCINE'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:50:40
User entered 'SHINGLES'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Please enter dose.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:38:55
Query 'Please enter dose.' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 00:45:31
User entered '0.5' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	10 Nov 2020 14:20:22
User opened query 'Please enter dose.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:51:01
User entered '1'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	11 Nov 2020 00:45:24
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	10 Nov 2020 14:20:22
User entered 'mL (mL)' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	10 Nov 2020 14:20:22
User entered 'Other (OTHER)'	(b) (4) Alicia Cevera (b) (4)	22 Oct 2020 19:27:00
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Un-verified.	(b) (4)	
	Albert Garcia (b) (4)	11 Nov 2020 00:45:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 00:45:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:51:06
User entered 'INJECTION'	Alicia Cevera (b) (4)	22 Oct 2020 19:27:00
	(b) (4)	

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:51:08
User entered 'once (ONCE)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:51:10
User entered empty.	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:51:15
User entered 'Intramuscular (INTRAMUSCULAR)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:51:17
User entered empty.	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:51:19
User entered '21 Oct 2020'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:51:22
User entered '0'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:51:23
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:51:25
User entered '21 Oct 2020'	Alicia Cevera (b) (4) (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User entered empty.	System	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User entered empty.	System	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:08:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:30
User entered empty.	System	22 Oct 2020 19:27:00

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:08:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:12
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	11 Nov 2020 00:49:53
User entered 'No (N)'	(b) (4)	
	Amber Vasquez (b) (4)	10 Oct 2020 22:17:12
	(b) (4)	

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:08:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered '9 Sep 2020'	Albert Garcia (b) (4)	11 Nov 2020 00:50:32
	(b) (4)	

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:08:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'HIP REPLACEMENT - RIGHT HIP'	(b) (4) Albert Garcia (b) (4) (b) (4)	11 Nov 2020 00:50:32

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered 'Medical History (MH)'	Albert Garcia (b) (4)	11 Nov 2020 00:50:32
	(b) (4)	

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:08:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 00:50:32
	(b) (4)	

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:08:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:32
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '09 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:55:36

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:08:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:32
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Preoperative bloodwork'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:55:36

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:32
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:55:36

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:08:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:32
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:55:36

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:08:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:38
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '09 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:57:14

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:08:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:38
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Xray- pelvis'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:57:14

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:38
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:49:11
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:29:34
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:57:14

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:08:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:38
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:57:14

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:08:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:44
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '03 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:59:47

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:08:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:48:37
User entered 'PREOP - CHEST X-RAY' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:48:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered 'Chest x-ray'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:59:47

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User closed query 'Per CDM - RQ: Please verify that indication recorded as Adverse Event however no corresponding AE is provided in AE page. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 10:09:22
Query 'Per CDM - RQ: Please verify that indication recorded as Adverse Event however no corresponding AE is provided in AE page. Please review and update accordingly. Else clarify.' answered with 'AE was created and in chart' (Site from DM).	Diana Toney (b) (4) (b) (4)	26 Mar 2021 19:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	26 Mar 2021 19:19:16
Signature has been broken.	Diana Toney (b) (4) (b) (4)	26 Mar 2021 19:18:33
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	26 Mar 2021 19:18:33
User opened query 'Per CDM - RQ: Please verify that indication recorded as Adverse Event however no corresponding AE is provided in AE page. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:12:42
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page within this timeframe. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 08:13:35
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page within this timeframe. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'updated term ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:48:47

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:08:31

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page within this timeframe. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	04 Mar 2021 10:29:54
	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:52:28
User entered 'Adverse Event (AE)'	gail lavine (b) (4) (b) (4)	02 Dec 2020 13:59:47

US3222315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:08:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:44
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:59:47

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered		
'USA-US104-2020-MRNA-1273-P301000002'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:24
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:46
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Bruce'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Lisa'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Tracy'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Rankin'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Holloway'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Kowalski'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '6550 Mapleridge Street'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '860 Peachwood Dr.'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Deland'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Houston'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'DELAND'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered empty.	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'TX'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'FLORIDA'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '32720'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '77081'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '32720'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:53:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:52
User entered 'US'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 13:21:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered '4'	System	03 Dec 2020 16:09:05
User entered '3'	System	12 Nov 2020 12:52:02
User entered '2'	System	12 Nov 2020 01:53:39
User entered '1'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered		
'USA-US104-2020-MRNA-1273-P301000002'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:24
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:46
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Bruce'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Lisa'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Tracy'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Rankin'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Holloway'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Kowalski'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '6550 Mapleridge Street'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '860 Peachwood Dr.'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Deland'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Houston'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'DELAND'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered empty.	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'TX'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'FLORIDA'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '32720'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '77081'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '32720'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:53:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:52
User entered 'US'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 13:21:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered '4'	System	03 Dec 2020 16:09:05
User entered '3'	System	12 Nov 2020 12:52:02
User entered '2'	System	12 Nov 2020 01:53:39
User entered '1'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:08:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '23/Sep/2020 21:35'	(b) (4) System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:08:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '1'	(b) (4), (b) (6)	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered		
'USA-US104-2020-MRNA-1273-P301000002'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:24
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:46
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Bruce'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Lisa'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Tracy'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Rankin'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Holloway'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Kowalski'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '6550 Mapleridge Street'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '860 Peachwood Dr.'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Deland'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Houston'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'DELAND'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered empty.	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'TX'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'FLORIDA'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '32720'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '77081'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '32720'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:53:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:52
User entered 'US'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 13:21:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered '4'	System	03 Dec 2020 16:09:05
User entered '3'	System	12 Nov 2020 12:52:02
User entered '2'	System	12 Nov 2020 01:53:39
User entered '1'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:08:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12/Nov/2020 01:53'	(b) (4) System	12 Nov 2020 01:53:39

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:08:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:51:50
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 01:53:39

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered		
'USA-US104-2020-MRNA-1273-P301000002'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:24
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:46
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Bruce'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Lisa'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Tracy'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Rankin'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Holloway'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Kowalski'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '6550 Mapleridge Street'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '860 Peachwood Dr.'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Deland'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Houston'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'DELAND'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered empty.	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'TX'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'FLORIDA'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '32720'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '77081'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '32720'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:53:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:52
User entered 'US'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 13:21:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered '4'	System	03 Dec 2020 16:09:05
User entered '3'	System	12 Nov 2020 12:52:02
User entered '2'	System	12 Nov 2020 01:53:39
User entered '1'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:08:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '12/Nov/2020 07:52'	(b) (4) System	12 Nov 2020 12:52:02

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:08:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:08:55
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 12:52:02

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered		
'USA-US104-2020-MRNA-1273-P301000002'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:24
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:46
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Bruce'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Lisa'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Tracy'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Rankin'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Holloway'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Kowalski'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '6550 Mapleridge Street'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '860 Peachwood Dr.'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Deland'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Houston'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'DELAND'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered empty.	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'TX'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'FLORIDA'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '32720'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '77081'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '32720'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:53:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:52
User entered 'US'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 13:21:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered '4'	System	03 Dec 2020 16:09:05
User entered '3'	System	12 Nov 2020 12:52:02
User entered '2'	System	12 Nov 2020 01:53:39
User entered '1'	System	24 Sep 2020 01:35:06

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:08:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '03/Dec/2020 11:09'	(b) (4) System	03 Dec 2020 16:09:05

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:08:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
User entered '1'	(b) (4), (b) (6)	03 Dec 2020 16:09:05

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered		
'USA-US104-2020-MRNA-1273-P301000002'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Yes (Y)'	System	24 Sep 2020 01:34:36

US3222315

Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:24
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:46
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'No (N)'	System	24 Sep 2020 01:34:36

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Bruce'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Lisa'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Tracy'	System	24 Sep 2020 01:34:36

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Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Rankin'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Holloway'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:34:59
User entered 'Kowalski'	System	24 Sep 2020 01:34:36

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '860 Peachwood Ave'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '6550 Mapleridge Street'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '860 Peachwood Dr.'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:08:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered 'Deland'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'Houston'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'DELAND'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

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Form: Safety Report Form

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Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered empty.	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered 'TX'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered 'FLORIDA'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

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Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
	(b) (4)	
Un-reviewed for Safety.	System	18 Mar 2021 13:21:50
Signature has been broken.	System	18 Mar 2021 13:21:50
User entered '32720'	System	18 Mar 2021 13:21:50
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 13:21:37
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 16:09:05
User entered '77081'	System	03 Dec 2020 16:09:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:51:50
Un-reviewed for Safety.	System	12 Nov 2020 01:53:39
User entered empty.	System	12 Nov 2020 01:53:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:53:27
User entered '32720'	Albert Garcia (b) (4)	11 Nov 2020 00:38:52
	(b) (4)	

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:53:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:52
User entered 'US'	System	24 Sep 2020 01:35:06

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 13:21:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:52:28
	(b) (4)	
User entered '4'	System	03 Dec 2020 16:09:05
User entered '3'	System	12 Nov 2020 12:52:02
User entered '2'	System	12 Nov 2020 01:53:39
User entered '1'	System	24 Sep 2020 01:35:06

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Form: Safety Report Form (5)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '18/Mar/2021 08:21'	(b) (4) System	18 Mar 2021 13:21:50

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Folder: SAE USA-US104-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:11:39
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:21:50