

US3332059 (Prod: Foothill Family Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:05:08

All time stamps listed in this document are displayed in GMT

US3332059

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

[Participant ID](#)

US3332059

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:29:53

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 18:29:54

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 18:29:53

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	LOW BACK PINCHED NERVE
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 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) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	HYPOERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 18:29:53

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	SPINAL DECOMPRESSIVE LAMINECTOMY
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	BENIGN SPINAL TUMOR (T3-T4)
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Condition	EXERCISE RELATED MUSCLE SORENESS
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:00 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:00
Height (<i>xxx.x</i>)	61.8 in
Weight (<i>xxx.x</i>)	122.4 lb
BMI (<i>xxx.x</i>)	22.57950 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

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) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

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 2011

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:29:54

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

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

What was the participant's randomization number? 188081

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) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

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) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:00
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	15:33 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 15:33
Temperature (xxx.x)	99.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

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) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

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) 15:02 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 15:02

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) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:20 (24 HR)
Collection date and time (derived)	24 AUG 2020 14:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

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	14:25	24 AUG 2020 14:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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 15:22

PC Close Date & Time

24 AUG 2020 17:52

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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 98.7 °F

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

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

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

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

PC Time Stamp 24 AUG 2020 22:33

PC Open Date & Time 24 AUG 2020 18:47

PC Close Date & Time 25 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

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

25 AUG 2020 19:50

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 13:00

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 18:05

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 14:14

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 AUG 2020 15:39

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

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 ☒

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 23:04

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 8

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 31 AUG 2020 12:59

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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 15:22

PC Close Date & Time

24 AUG 2020 17:52

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

24 AUG 2020 22:35

PC Open Date & Time

24 AUG 2020 18:47

PC Close Date & Time

25 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

25 AUG 2020 19:51

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

26 AUG 2020 12:59

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

27 AUG 2020 18:06

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

28 AUG 2020 14:14

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

29 AUG 2020 15:39

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

30 AUG 2020 23:04

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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 15:22

PC Close Date & Time

24 AUG 2020 17:52

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 22:34
PC Open Date & Time	24 AUG 2020 18:47
PC Close Date & Time	25 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

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)

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:51
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

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 ☒

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:06
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

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 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 14:15
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

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 ☒

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 15:40
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 23:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3332059

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 12:59
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3332059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:30
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	15:13 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 15:13
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	53 mmHg
Diastolic Blood Pressure units	MMHG

US3332059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 14:42 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 14:42

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

US3332059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	13:45 (24 HR)
Collection date and time (derived)	18 SEP 2020 13:45

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:42	18 SEP 2020 13:42
Nasopharyngeal Swab 2	No		

US3332059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 15:15

PC Open Date & Time

18 SEP 2020 15:02

PC Close Date & Time

18 SEP 2020 17:32

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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 97.4 °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	18 SEP 2020 21:12
PC Open Date & Time	18 SEP 2020 18:27
PC Close Date & Time	19 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	19 SEP 2020 12:04
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 13:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:43

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

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 ☒

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 08:12

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

23 SEP 2020 12:30

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 12:42

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 15:15

PC Open Date & Time

18 SEP 2020 15:02

PC Close Date & Time

18 SEP 2020 17:32

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

25

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

18 SEP 2020 21:12

PC Open Date & Time

18 SEP 2020 18:27

PC Close Date & Time

19 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

25

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

19 SEP 2020 12:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

20 SEP 2020 13:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

21 SEP 2020 12:43

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

23 SEP 2020 08:12

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

23 SEP 2020 12:31

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

24 SEP 2020 12:43

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 15:16
PC Open Date & Time	18 SEP 2020 15:02
PC Close Date & Time	18 SEP 2020 17:32

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 21:13
PC Open Date & Time	18 SEP 2020 18:27
PC Close Date & Time	19 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

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)

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:06
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

110 of 2620

EAB) (1725)

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 13:57
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

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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US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:43
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 08:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

116 of 2620

EAB) (1725)

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:31
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

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)

118 of 2620

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 12:43
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:08

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

25 SEP 2020 14:00

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

26 SEP 2020 16:27

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 10

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

27 SEP 2020 14:11

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 11

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

28 SEP 2020 18:31

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 12

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

29 SEP 2020 13:15

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 14:00
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 SEP 2020 16:28
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 SEP 2020 14:11
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 18:31
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 13:15
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3332059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:53

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:25
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3332059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	13:45 (24 HR)
Collection date and time (derived)	13 OCT 2020 13:45

US3332059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:29:54

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 OCT 2020 07:48:27
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 09:45:30

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 08:05:02

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 16:50:57
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 18:00:12
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 07:20:03

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 16:29:09
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 08:10:43

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 16:53:54

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 17:06:23
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 12:00:42

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 17:58:19

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 08:43:42
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 08:15:18

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 FEB 2021 08:36:39
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 01:08:41

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 MAR 2021 07:59:36
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 MAR 2021 07:06:08
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 08:34:30

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 07:46:23

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 07:12:37

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 12:09:32

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 12:00:20
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 07:50:52

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 APR 2021 12:01:07
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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°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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUN 2021 00:01
Patient Cloud Close Date & Time	13 JUN 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2021 00:01
Patient Cloud Close Date & Time	08 AUG 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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°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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Patient Cloud Open Date & Time	13 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JAN 2022 00:01
Patient Cloud Close Date & Time	09 JAN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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°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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Patient Cloud Open Date & Time	23 FEB 2022 00:01
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Patient Cloud Close Date & Time	27 FEB 2022 23:59
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US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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°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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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°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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission	
Patient Cloud Open Date & Time	24 AUG 2022 00:01
Patient Cloud Close Date & Time	28 AUG 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission	
Patient Cloud Open Date & Time	21 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission	
Patient Cloud Open Date & Time	28 SEP 2022 00:01
Patient Cloud Close Date & Time	02 OCT 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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°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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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°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 ☐

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Date and time of submission

Patient Cloud Open Date & Time	26 OCT 2022 00:01
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Patient Cloud Close Date & Time	30 OCT 2022 23:59
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US3332059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:05:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 01:08:55

US3332059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

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) _____

US3332059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 MAR 2021

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

US3332059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	3 MAR 2021 08:35

US3332059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:50:25

Generated On: 09 Jun 2021 17:05:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332059

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:50:25

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332059

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

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Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:05:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

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

Visit date (dd MMM yyyy)	3 MAR 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:05:16

Generated On: 09 Jun 2021 17:05:08

Date of updated informed consent (*dd MMM yyyy*) 3 MAR 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 3 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	3 MAR 2021
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Collection time (00:00-23:59)	08:35 (24 HR)
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Collection date and time (derived)	3 MAR 2021 08:35
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US3332059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00 - 23:59)	08:33
Collection Date and Time (derived)	3 MAR 2021 08:33

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

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) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 SEP 2020
Start time (00:00-23:59)	10:00 (24 HR)
AE start date and time (derived)	18 SEP 2020 10:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 SEP 2020
End time (00:00-23:59)	09:00 (24 HR)
AE End Date and Time (derived)	29 SEP 2020 09:00
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

AEID

Adverse event

NOSE BLEEDS-INTERMITTENT
EPISTAXIS

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)

17 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

AEID	USA-US202-2021-MRNA-1273-P30 1000006
Adverse event	MULTIPLE PELVIC FRACTURES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

Number of Days in ICU	
Persistent or significant disability or incapacity	True
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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 (4)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

AEID	USA-US202-2021-MRNA-1273-P30 1000006
Adverse event	RIGHT RIBS #4-8 FRACTURES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	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 (5)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

AEID	USA-US202-2021-MRNA-1273-P30 1000006
Adverse event	CLOSED SACRAL FRACTURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

AEID	USA-US202-2021-MRNA-1273-P30 1000006
Adverse event	RIGHT ACETABULAR FRACTURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 14:45:40

Generated On: 09 Jun 2021 17:05:08

Number of Days in ICU	
Persistent or significant disability or incapacity	True
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 13:33:48

Generated On: 09 Jun 2021 17:05:08

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication ESCITALOPRAM OXALATE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication SUMATRIPTAN SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 OCT 2010
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 14:45:41

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Name of Medication PROLIA

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 MONTHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 14:45:41

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 14:45:41

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Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication CENTRUM SILVER

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication KRILL OIL

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication NAPROXEN SODIUM

Prophylaxis Yes ☐
No ☒

Indication LOW BACK PINCHED NERVE

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication EXERCISE RELATED MUSCLE SORENESS

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication HEADACHE, MUSCLE ACHES,
JOINT PAIN

Dose per administration 440

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 (10)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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 (11)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PROPHYLAXIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE PELVIC FRACTURES,
R RIBS 4-8 FRACTURES

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 14:45:41

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE PELVIC FRACTURES,
R RIBS 4-8 FRACTURES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

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 (15)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE PELVIC FRACTURES,
R RIBS 4-8 FRACTURES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication IOPAMIDOL

Prophylaxis Yes ☐
No ☒

Indication CT CONTRAST

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication ARTIFICIAL TEARS

Prophylaxis Yes ☐
No ☒

Indication BILATERAL DRY EYES

Dose per administration 2

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

If dose unit is Other, specify DROPS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication MIRALAX

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☒
No ☐

Indication DEHYDRATION PROPHYLAXIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		22 APR 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☒
No ☐

Indication MEDICATION FLUSH

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 (22)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication BISACODYL

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication DOCUSATE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS

Dose per administration 283

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication DOCUSATE-SENNA

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS

Dose per administration 50-8.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

412 of 2620

EAB) (1725)

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication CLOTTING PROPHYLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

414 of 2620

EAB) (1725)

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE PELVIS FRACTURES,
R RIBS 4-8 FRACTURES

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 00:11:30

Generated On: 09 Jun 2021 17:05:08

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 May 2021 14:45:41

Generated On: 09 Jun 2021 17:05:08

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 MAR 2021	NASAL CAUTERIZATION	Adverse Event	
22 APR 2021	CT SCAN CERVICAL SPINE	Adverse Event	
22 APR 2021	CT SCAN THORAX	Adverse Event	
22 APR 2021	CT SCAN CERVICAL SPINE	Adverse Event	
22 APR 2021	CT SCAN THORAX	Adverse Event	

US3332059

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:05:08

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

US3332059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:05:08

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 ☐

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 14:45:42

Generated On: 09 Jun 2021 17:05:08

SAEID	USA-US202-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 14:45:42

Generated On: 09 Jun 2021 17:05:08

SAEID	USA-US202-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	30/APR/2021 09:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3332059 (Prod: Foothill Family Clinic)

US3332059

Form: Participant Creation

Generated On: 09 Jun 2021 17:05:08

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'US3332059'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:24:30

US3332059

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 21:24:04

US3332059

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '24 AUG 2020'	RWS_ENDPOINT	24 Aug 2020 20:24:31
	ENDPOINT (b) (4)	

US3332059

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 21:24:04

US3332059

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'SCRN'	System	24 Aug 2020 21:24:04

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered (b) (6) 1954'	RWS_ENDPOINT	24 Aug 2020 20:24:32
	ENDPOINT (b) (4)	

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '66'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'YEARS'	System	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '66'	System	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Female (F)'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 21:24:46

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Aug 2020'	System	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2020'	System	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 07:06:15
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'Data entry error.' (Site from DM).	Ty Henry (b) (4)	18 Sep 2020 21:26:27
	(b) (4)	
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Ty Henry (b) (4)	18 Sep 2020 21:26:18
	(b) (4)	
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 05:48:58
User entered 'Amendment 5 (5)'	(b) (4), (b) (6)	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	RWS_ENDPOINT	24 Aug 2020 20:24:31
	ENDPOINT (b) (4)	

US3332059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1'	System	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 21:23:17

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Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:05:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:15:47

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:17:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:17:44
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:16:58
User entered 'anxiety'	(b) (4), (b) (6)	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2010'	(b) (4), (b) (6)	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2010'	System	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2010'	System	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:16:06

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:17:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:17:44
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:16:58
User entered 'osteoporosis'	(b) (4), (b) (6)	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1996'	(b) (4), (b) (6)	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1996'	System	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1996'	System	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:16:30

US3332059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Pinched nerve - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 08:55:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 08:55:37
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:16:58
User entered 'low back pinched nerve'	(b) (4), (b) (6)	24 Aug 2020 23:16:51

US3332059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1977'	(b) (4), (b) (6)	24 Aug 2020 23:16:51

US3332059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:16:51

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:16:51

US3332059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:16:51

US3332059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:16:51

US3332059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1977'	System	24 Aug 2020 23:16:51

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1977'	System	24 Aug 2020 23:16:51

US3332059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:16:51

US3332059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:16:51

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:18:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:18:46
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:18:01
User entered 'migraines'	(b) (4), (b) (6)	24 Aug 2020 23:17:09

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2010'	(b) (4), (b) (6)	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2010'	System	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2010'	System	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:17:09

US3332059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
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)	24 Aug 2020 23:18:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:18:46
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:18:01
User entered 'depression'	(b) (4), (b) (6)	24 Aug 2020 23:17:31

US3332059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2013'	(b) (4), (b) (6)	24 Aug 2020 23:17:31

US3332059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:17:31

US3332059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:17:31

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:17:31

US3332059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:17:31

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2013'	System	24 Aug 2020 23:17:31

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2013'	System	24 Aug 2020 23:17:31

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:17:31

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:17:31

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:18:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:18:46
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:18:02
User entered 'seasonal allergies'	(b) (4), (b) (6)	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1980'	(b) (4), (b) (6)	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1980'	System	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1980'	System	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:17:55

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
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)	25 Aug 2020 08:04:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 08:04:41
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:19:03
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2011'	(b) (4), (b) (6)	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2011'	System	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2011'	System	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:18:22

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 00:31:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 00:31:38
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:19:04
User entered 'bilateral hearing lloss'	(b) (4), (b) (6)	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2015'	(b) (4), (b) (6)	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2015'	System	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2015'	System	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:18:42

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:19:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:19:47
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:19:04
User entered 'vitamin d deficiency'	(b) (4), (b) (6)	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1996'	(b) (4), (b) (6)	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1996'	System	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1996'	System	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:19:03

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:20:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 23:20:38
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:20:06
User entered 'postmenopausal'	(b) (4), (b) (6)	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2011'	(b) (4), (b) (6)	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2011'	System	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2011'	System	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	24 Aug 2020 23:19:21

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal laminectomy, LLT: Spinal laminectomy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:43:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:43:32
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 23:20:06
User entered 'spinal decompressive laminectomy'	(b) (4), (b) (6)	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1977'	(b) (4), (b) (6)	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:24:25
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Data entry error.' (Site from DM).	Ty Henry (b) (4)	28 Sep 2020 20:20:53
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Ty Henry (b) (4)	28 Sep 2020 20:20:44
	(b) (4)	
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 03:53:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1977' reason for change:	Ty Henry (b) (4)	28 Sep 2020 20:20:44
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1977'	System	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1977'	System	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1977'	System	28 Sep 2020 20:20:44
User entered empty.	System	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1977'	System	28 Sep 2020 20:20:44
User entered empty.	System	24 Aug 2020 23:19:46

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms benign, HLT: Nervous system neoplasms benign NEC, PT: Benign neoplasm of spinal cord, LLT: Benign neoplasm of spinal cord - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 11:46:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 11:46:46
Data point term sent to Coder	System	18 Sep 2020 21:30:44
User closed query 'For coding purpose: Please clarify more precisely location of tumor (Vertebral column, Spinal cord etc.), indicate if they are benign or malignant & update the term.' (Site from System).	System	18 Sep 2020 21:30:07
Query 'For coding purpose: Please clarify more precisely location of tumor (Vertebral column, Spinal cord etc.), indicate if they are benign or malignant & update the term.' answered with 'Benign, updated. Location is T3-T4.' (Site from System).	Ty Henry (b) (4)	18 Sep 2020 21:30:07
User entered 'BENIGN SPINAL TUMOR (T3-T4)' reason for change: Data Entry Error	Ty Henry (b) (4)	18 Sep 2020 21:29:44
User opened query 'For coding purpose: Please clarify more precisely location of tumor (Vertebral column, Spinal cord etc.), indicate if they are benign or malignant & update the term.' (Site from System).	Coder Import (b) (4)	11 Sep 2020 11:25:29
Data point term sent to Coder	System	24 Aug 2020 23:21:07
User entered 'spinal tumor (t3-t4)'	(b) (4), (b) (6)	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1977'	(b) (4), (b) (6)	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1977'	(b) (4), (b) (6)	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1977'	System	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1977'	System	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1977'	System	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1977'	System	24 Aug 2020 23:20:18

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle soreness - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 07:10:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 07:10:50
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:22:12
User entered 'Exercise Related Muscle Soreness'	Ty Henry (b) (4)	18 Sep 2020 19:22:11
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 1980'	Ty Henry (b) (4)	18 Sep 2020 19:22:11
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	18 Sep 2020 19:22:11
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	18 Sep 2020 19:22:11
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	18 Sep 2020 19:22:11
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	18 Sep 2020 19:22:11
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 1980'	System	18 Sep 2020 19:22:11

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '1980'	System	18 Sep 2020 19:22:11

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	18 Sep 2020 19:22:11

US3332059

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	18 Sep 2020 19:22:11

US3332059

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
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: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	23 Jan 2021 18:43:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Jan 2021 18:43:04
	(b) (4)	
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 antibiotics - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:03:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:03:09
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 18:53:02
User entered 'nitrofurantoin intolerance'	Colby Bostock (b) (4)	08 Oct 2020 18:53:00
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2007'	Colby Bostock (b) (4)	08 Oct 2020 18:53:00
	(b) (4)	

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:53:00
	(b) (4)	

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	Colby Bostock (b) (4)	08 Oct 2020 18:53:00
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	08 Oct 2020 18:53:00
	(b) (4)	

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:53:00
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2007'	System	08 Oct 2020 18:53:00

US3332059

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2007'	System	08 Oct 2020 18:53:00

US3332059

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:53:00

US3332059

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:53:00

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:58:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:58:34
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 18:54:03
User entered 'allergy- sulfa drugs'	Colby Bostock (b) (4)	08 Oct 2020 18:53:19
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2007'	Colby Bostock (b) (4)	08 Oct 2020 18:53:19
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:53:19
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	Colby Bostock (b) (4)	08 Oct 2020 18:53:19
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	08 Oct 2020 18:53:19
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:53:19
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2007'	System	08 Oct 2020 18:53:19

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2007'	System	08 Oct 2020 18:53:19

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:53:19

US3332059

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:53:19

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
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: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 12:23:19
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Oct 2020 12:23:19
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 18:54:04
User entered 'sulfamethoxazole allergy'	Colby Bostock (b) (4)	08 Oct 2020 18:53:40
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2007'	Colby Bostock (b) (4)	08 Oct 2020 18:53:40
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:53:40
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	Colby Bostock (b) (4)	08 Oct 2020 18:53:40
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	08 Oct 2020 18:53:40
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:53:40
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2007'	System	08 Oct 2020 18:53:40

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2007'	System	08 Oct 2020 18:53:40

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:53:40

US3332059

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:53:40

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
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: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:58:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:58:35
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 18:54:05
User entered 'trimethoprim allergy'	Colby Bostock (b) (4)	08 Oct 2020 18:54:03
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2007'	Colby Bostock (b) (4)	08 Oct 2020 18:54:03
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:54:03
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	Colby Bostock (b) (4)	08 Oct 2020 18:54:03
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	08 Oct 2020 18:54:03
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:54:03
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2007'	System	08 Oct 2020 18:54:03

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2007'	System	08 Oct 2020 18:54:03

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:54:03

US3332059

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:54:03

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Drug intolerance, LLT: Drug intolerance - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 09:37:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 09:37:22
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 18:55:05
User entered 'venlafaxine hcl intolerance'	Colby Bostock (b) (4)	08 Oct 2020 18:54:23
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2000'	Colby Bostock (b) (4)	08 Oct 2020 18:54:23
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:54:23
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	Colby Bostock (b) (4)	08 Oct 2020 18:54:23
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	08 Oct 2020 18:54:23
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	08 Oct 2020 18:54:23
	(b) (4)	

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'Jan 2000'	System	08 Oct 2020 18:54:23

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '2000'	System	08 Oct 2020 18:54:23

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:54:23

US3332059

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered empty.	System	08 Oct 2020 18:54:23

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '14:00'	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered '24 Aug 2020 14:00'	System	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '61.8' in	(b) (4), (b) (6)	24 Aug 2020 23:21:29
DataPoint set to visible.	System	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '122.4' lb	(b) (4), (b) (6)	24 Aug 2020 23:21:29
DataPoint set to visible.	System	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
Amendment Manager: User entered '22.57950'	System	17 Sep 2020 00:21:58
User entered '22.6'	System	24 Aug 2020 23:21:29
DataPoint set to visible.	System	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'kg/m2'	System	24 Aug 2020 23:21:29
DataPoint set to visible.	System	24 Aug 2020 21:25:07

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:16:41
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4)	25 Sep 2020 21:37:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 21:37:32
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:08:43
User entered '99.1' F	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	25 Sep 2020 21:37:32
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4)	25 Sep 2020 21:37:32
	(b) (4)	
User entered '58'	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'bpm'	System	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4)	25 Sep 2020 21:37:32
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'breaths/min'	System	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4)	25 Sep 2020 21:37:32
	(b) (4)	
User entered '103'	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'mmHg'	System	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4)	25 Sep 2020 21:37:32
	(b) (4)	
User entered '62'	(b) (4), (b) (6)	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User entered 'mmHg'	System	24 Aug 2020 23:21:29

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35

US3332059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35

US3332059

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:21:38

US3332059

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 23:21:38

US3332059

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 23:22:00

US3332059

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:08

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:00

US3332059

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:08

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	24 Aug 2020 23:22:00

US3332059

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:08

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:22:00

US3332059

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:22:00

US3332059

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:08

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:22:00

US3332059

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'un UNK 2011'	(b) (4), (b) (6)	24 Aug 2020 23:22:00

US3332059

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:08

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:22:00

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

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 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:04:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 23:22:37

US3332059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:23:56

US3332059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:23:56

US3332059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:23:56

US3332059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'VISIT1'	System	24 Aug 2020 21:23:56

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:39:28

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '188081'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:39:28

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:39:28

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:23:35

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:23:35

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:23:35

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:23:35

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:23:35

US3332059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:08

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 06:01:52
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'field completed' (Site from DM).	Megan Grimmatt (b) (4) (b) (4)	15 Dec 2020 00:03:32
User entered 'No (N)'	Megan Grimmatt (b) (4) (b) (4)	15 Dec 2020 00:03:29
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:21:12
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:45:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:45:16

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:16:45
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	25 Sep 2020 21:53:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	25 Sep 2020 21:53:30
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:08:23
User entered '61.8' in	(b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 21:53:30
User entered '122.4' lb	(b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:16:45
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	25 Sep 2020 21:53:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	25 Sep 2020 21:53:30
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:08:23
User entered '61.8' in	(b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 21:53:30
User entered '122.4' lb	(b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '14:00'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '24 Aug 2020 14:00'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '58'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'bpm'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'breaths/min'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '103'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '62'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:16:45
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	25 Sep 2020 21:53:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	25 Sep 2020 21:53:30
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:08:23
User entered '61.8' in	(b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 21:53:30
User entered '122.4' lb	(b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '15:33'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '24 Aug 2020 15:33'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '99.6' F	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '54'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'bpm'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'breaths/min'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '102'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '63'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	24 Aug 2020 23:24:23

US3332059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:30

US3332059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:30

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '15:02'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '24 Aug 2020 15:02'	System	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'ONCE'	System	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 21:25:51

US3332059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:45

US3332059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:24:45

US3332059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '14:20' reason for change: Data Entry Error	(b) (4)	24 Aug 2020 23:25:15
User entered '14:25'	(b) (4), (b) (6)	24 Aug 2020 23:24:45

US3332059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '24 Aug 2020 14:20'	System	24 Aug 2020 23:25:15
User entered '24 Aug 2020 14:25'	System	24 Aug 2020 23:24:45

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '14:25'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '24 Aug 2020 14:25'	System	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered empty.	System	24 Aug 2020 23:25:04

US3332059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:25:22

US3332059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	24 Aug 2020 23:25:22

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 15:22'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 17:52'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:33:20', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f1c783e3-bd46-46cf-95f3-b08cdbcad73e' User entered 'Yes (Y)'	System	25 Aug 2020 04:33:53
	System	25 Aug 2020 04:33:53

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:33:29', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f1c783e3-bd46-46cf-95f3-b08cdbcad73e' User entered '98.7'	System	25 Aug 2020 04:33:53
	System	25 Aug 2020 04:33:53

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:33:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f1c783e3-bd46-46cf-95f3-b08cdbcad73e'	System	25 Aug 2020 04:33:53
User entered 'Yes (Y)'	System	25 Aug 2020 04:33:53

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data will be updated as appropriate.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:51:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Ty Henry (b) (4)	09 Sep 2020 16:37:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:33:39', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f1c783e3-bd46-46cf-95f3-b08cdbcad73e'	(b) (4)	
User entered '1'	System	25 Aug 2020 04:33:53
	System	25 Aug 2020 04:33:53
	System	25 Aug 2020 04:33:53

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:33:39', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f1c783e3-bd46-46cf-95f3-b08cdbcad73e' User entered '0'	System	25 Aug 2020 04:33:53
	System	25 Aug 2020 04:33:53

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:33:47', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f1c783e3-bd46-46cf-95f3-b08cdbcad73e' User entered '24 Aug 2020 22:33'	System	25 Aug 2020 04:33:53
	System	25 Aug 2020 04:33:53

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 18:47'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 2'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:48:49', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b68d2f1b-08d0-43d6-9f36-69959b3bf41f' User entered 'Yes (Y)'	System	26 Aug 2020 01:50:58
	System	26 Aug 2020 01:50:58

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:50:49', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b68d2f1b-08d0-43d6-9f36-69959b3bf41f' User entered '97.4'	System	26 Aug 2020 01:50:58
	System	26 Aug 2020 01:50:58

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:50:52', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b68d2f1b-08d0-43d6-9f36-69959b3bf41f' User entered 'No (N)'	System	26 Aug 2020 01:50:58
	System	26 Aug 2020 01:50:58

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:50:56', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b68d2f1b-08d0-43d6-9f36-69959b3bf41f' User entered '25 Aug 2020 19:50'	System	26 Aug 2020 01:50:58
	System	26 Aug 2020 01:50:58

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 3'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:59:42', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3ccee0da-8201-417a-87e2-6b9e2bcfd55d' User entered 'Yes (Y)'	System	26 Aug 2020 19:00:43
	System	26 Aug 2020 19:00:43

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T13:00:32', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3ccee0da-8201-417a-87e2-6b9e2bcfd55d' User entered '98.4'	System	26 Aug 2020 19:00:43
	System	26 Aug 2020 19:00:43

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T13:00:35', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3ccee0da-8201-417a-87e2-6b9e2bcfd55d' User entered 'No (N)'	System	26 Aug 2020 19:00:43
	System	26 Aug 2020 19:00:43

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T13:00:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3ccee0da-8201-417a-87e2-6b9e2bcfd55d' User entered '26 Aug 2020 13:00'	System	26 Aug 2020 19:00:43
	System	26 Aug 2020 19:00:43

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 4'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:05:32', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '5a7f1bad-3b14-4232-b4d8-af2675892795'	System	28 Aug 2020 00:05:50
User entered 'Yes (Y)'	System	28 Aug 2020 00:05:50

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:05:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '5a7f1bad-3b14-4232-b4d8-af2675892795' User entered '98.2'	System	28 Aug 2020 00:05:50
	System	28 Aug 2020 00:05:50

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:05:43', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '5a7f1bad-3b14-4232-b4d8-af2675892795'	System	28 Aug 2020 00:05:50
User entered 'No (N)'	System	28 Aug 2020 00:05:50

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:05:46', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '5a7f1bad-3b14-4232-b4d8-af2675892795'	System	28 Aug 2020 00:05:50
User entered '27 Aug 2020 18:05'	System	28 Aug 2020 00:05:50

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 5'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:04', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ec4ed2ff-20b1-4d87-b230-91de33906fce' User entered 'Yes (Y)'	System	28 Aug 2020 20:14:20
	System	28 Aug 2020 20:14:20

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:09', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ec4ed2ff-20b1-4d87-b230-91de33906fce' User entered '98.1'	System	28 Aug 2020 20:14:20
	System	28 Aug 2020 20:14:20

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:13', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ec4ed2ff-20b1-4d87-b230-91de33906fce'	System	28 Aug 2020 20:14:20
User entered 'No (N)'	System	28 Aug 2020 20:14:20

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:17', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ec4ed2ff-20b1-4d87-b230-91de33906fce' User entered '28 Aug 2020 14:14'	System	28 Aug 2020 20:14:20
	System	28 Aug 2020 20:14:20

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 6'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:38:43', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '78c60c86-6459-4341-9e8f-3334b783484f' User entered 'Yes (Y)'	System	29 Aug 2020 21:39:08
	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:38:53', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '78c60c86-6459-4341-9e8f-3334b783484f' User entered '97.4'	System	29 Aug 2020 21:39:08
	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:38:58', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '78c60c86-6459-4341-9e8f-3334b783484f' User entered 'Yes (Y)'	System	29 Aug 2020 21:39:08
	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data will be updated as appropriate.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:52:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Ty Henry (b) (4)	09 Sep 2020 16:38:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:02', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '78c60c86-6459-4341-9e8f-3334b783484f'	(b) (4)	
User entered '1'	System	29 Aug 2020 21:39:08
	System	29 Aug 2020 21:39:08
	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:02', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '78c60c86-6459-4341-9e8f-3334b783484f' User entered '0'	System	29 Aug 2020 21:39:08
	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:06', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '78c60c86-6459-4341-9e8f-3334b783484f' User entered '29 Aug 2020 15:39'	System	29 Aug 2020 21:39:08
	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 7'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b3637817-3ee4-47d3-9455-7e8375de6dfb' User entered 'No (N)'	System	31 Aug 2020 05:04:48
	System	31 Aug 2020 05:04:48

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:43', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b3637817-3ee4-47d3-9455-7e8375de6dfb' User entered 'No (N)'	System	31 Aug 2020 05:04:48
	System	31 Aug 2020 05:04:48

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:46', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b3637817-3ee4-47d3-9455-7e8375de6dfb' User entered '30 Aug 2020 23:04'	System	31 Aug 2020 05:04:48
	System	31 Aug 2020 05:04:48

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	29 Aug 2020 21:39:08
User entered 'Day 8'	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-31T12:59:29', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3ad72fa0-ec96-41fb-9f61-855b9fb06a23'	System	31 Aug 2020 18:59:41
User entered 'No (N)'	System	31 Aug 2020 18:59:41

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-31T12:59:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3ad72fa0-ec96-41fb-9f61-855b9fb06a23'	System	31 Aug 2020 18:59:41
User entered 'No (N)'	System	31 Aug 2020 18:59:41

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-31T12:59:37', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3ad72fa0-ec96-41fb-9f61-855b9fb06a23'	System	31 Aug 2020 18:59:41
User entered '31 Aug 2020 12:59'	System	31 Aug 2020 18:59:41

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 15:22'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 17:52'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0a983831-9372-4ff6-9cf0-405dff0b6a87'	System	25 Aug 2020 04:35:26
User entered 'None (1)'	System	25 Aug 2020 04:35:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:50', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0a983831-9372-4ff6-9cf0-405dff0b6a87' User entered 'No (N)'	System	25 Aug 2020 04:35:26
	System	25 Aug 2020 04:35:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:53', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0a983831-9372-4ff6-9cf0-405dff0b6a87'	System	25 Aug 2020 04:35:26
User entered 'No (N)'	System	25 Aug 2020 04:35:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:35:08', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0a983831-9372-4ff6-9cf0-405dff0b6a87'	System	25 Aug 2020 04:35:26
User entered 'None (1)'	System	25 Aug 2020 04:35:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:35:14', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0a983831-9372-4ff6-9cf0-405dff0b6a87'	System	25 Aug 2020 04:35:26
User entered '24 Aug 2020 22:35'	System	25 Aug 2020 04:35:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 18:47'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 2'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68c74e46-6167-4558-a842-cae99d47007b' User entered 'None (1)'	System	26 Aug 2020 01:51:15
	System	26 Aug 2020 01:51:15

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:03', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68c74e46-6167-4558-a842-cae99d47007b' User entered 'No (N)'	System	26 Aug 2020 01:51:15
	System	26 Aug 2020 01:51:15

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:05', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68c74e46-6167-4558-a842-cae99d47007b' User entered 'No (N)'	System	26 Aug 2020 01:51:15
	System	26 Aug 2020 01:51:15

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:09', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68c74e46-6167-4558-a842-cae99d47007b' User entered 'None (1)'	System	26 Aug 2020 01:51:15
	System	26 Aug 2020 01:51:15

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:12', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68c74e46-6167-4558-a842-cae99d47007b' User entered '25 Aug 2020 19:51'	System	26 Aug 2020 01:51:15
	System	26 Aug 2020 01:51:15

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 3'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:59:10', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '50b89b90-fb3e-47c7-b926-5e438779376c' User entered 'None (1)'	System	26 Aug 2020 19:00:14
	System	26 Aug 2020 19:00:14

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:59:13', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '50b89b90-fb3e-47c7-b926-5e438779376c' User entered 'No (N)'	System	26 Aug 2020 19:00:14
	System	26 Aug 2020 19:00:14

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:59:15', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '50b89b90-fb3e-47c7-b926-5e438779376c' User entered 'No (N)'	System	26 Aug 2020 19:00:14
	System	26 Aug 2020 19:00:14

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:59:18', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '50b89b90-fb3e-47c7-b926-5e438779376c' User entered 'None (1)'	System	26 Aug 2020 19:00:14
	System	26 Aug 2020 19:00:14

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:59:21', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '50b89b90-fb3e-47c7-b926-5e438779376c' User entered '26 Aug 2020 12:59'	System	26 Aug 2020 19:00:14
	System	26 Aug 2020 19:00:14

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 4'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:05:50', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3da4f1e7-0f4e-439e-8196-65482ec70529' User entered 'None (1)'	System	28 Aug 2020 00:06:05
	System	28 Aug 2020 00:06:05

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:05:53', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3da4f1e7-0f4e-439e-8196-65482ec70529' User entered 'No (N)'	System	28 Aug 2020 00:06:05
	System	28 Aug 2020 00:06:05

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:05:55', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3da4f1e7-0f4e-439e-8196-65482ec70529' User entered 'No (N)'	System	28 Aug 2020 00:06:05
	System	28 Aug 2020 00:06:05

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:05:58', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3da4f1e7-0f4e-439e-8196-65482ec70529' User entered 'None (1)'	System	28 Aug 2020 00:06:05
	System	28 Aug 2020 00:06:05

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:02', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3da4f1e7-0f4e-439e-8196-65482ec70529'	System	28 Aug 2020 00:06:05
User entered '27 Aug 2020 18:06'	System	28 Aug 2020 00:06:05

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 5'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:21', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '87fcbd7e-fa46-4ad2-824a-8c8ece030d76'	System	28 Aug 2020 20:14:35
User entered 'None (1)'	System	28 Aug 2020 20:14:35

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:24', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '87fcbd7e-fa46-4ad2-824a-8c8ece030d76'	System	28 Aug 2020 20:14:35
User entered 'No (N)'	System	28 Aug 2020 20:14:35

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '87fcbd7e-fa46-4ad2-824a-8c8ece030d76'	System	28 Aug 2020 20:14:35
User entered 'No (N)'	System	28 Aug 2020 20:14:35

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:30', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '87fcbd7e-fa46-4ad2-824a-8c8ece030d76'	System	28 Aug 2020 20:14:35
User entered 'None (1)'	System	28 Aug 2020 20:14:35

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '87fcbd7e-fa46-4ad2-824a-8c8ece030d76'	System	28 Aug 2020 20:14:35
User entered '28 Aug 2020 14:14'	System	28 Aug 2020 20:14:35

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 6'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:13', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '36b1e967-2a2a-43bc-9ff5-f6b82e004426'	System	29 Aug 2020 21:39:26
User entered 'None (1)'	System	29 Aug 2020 21:39:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:15', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '36b1e967-2a2a-43bc-9ff5-f6b82e004426'	System	29 Aug 2020 21:39:26
User entered 'No (N)'	System	29 Aug 2020 21:39:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:18', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '36b1e967-2a2a-43bc-9ff5-f6b82e004426'	System	29 Aug 2020 21:39:26
User entered 'No (N)'	System	29 Aug 2020 21:39:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:20', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '36b1e967-2a2a-43bc-9ff5-f6b82e004426'	System	29 Aug 2020 21:39:26
User entered 'None (1)'	System	29 Aug 2020 21:39:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:24', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '36b1e967-2a2a-43bc-9ff5-f6b82e004426' User entered '29 Aug 2020 15:39'	System	29 Aug 2020 21:39:26
	System	29 Aug 2020 21:39:26

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 7'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'bf15778e-ce94-4271-98c7-eff34b2b49ab'	System	31 Aug 2020 05:04:39
User entered 'None (1)'	System	31 Aug 2020 05:04:39

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:28', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'bf15778e-ce94-4271-98c7-eff34b2b49ab' User entered 'No (N)'	System	31 Aug 2020 05:04:39
	System	31 Aug 2020 05:04:39

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:31', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'bf15778e-ce94-4271-98c7-eff34b2b49ab' User entered 'No (N)'	System	31 Aug 2020 05:04:39
	System	31 Aug 2020 05:04:39

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'bf15778e-ce94-4271-98c7-eff34b2b49ab'	System	31 Aug 2020 05:04:39
User entered 'None (1)'	System	31 Aug 2020 05:04:39

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:36', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'bf15778e-ce94-4271-98c7-eff34b2b49ab' User entered '30 Aug 2020 23:04'	System	31 Aug 2020 05:04:39
	System	31 Aug 2020 05:04:39

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 15:22'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 17:52'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:07', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f57e6582-1f17-4d25-89c3-d99db962bffc' User entered 'None (0)'	System	25 Aug 2020 04:34:35
	System	25 Aug 2020 04:34:35

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:11', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f57e6582-1f17-4d25-89c3-d99db962bffc'	System	25 Aug 2020 04:34:35
User entered 'None (0)'	System	25 Aug 2020 04:34:35

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:14', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f57e6582-1f17-4d25-89c3-d99db962bffc' User entered 'None (0)'	System	25 Aug 2020 04:34:35
	System	25 Aug 2020 04:34:35

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:17', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f57e6582-1f17-4d25-89c3-d99db962bffc' User entered 'None (0)'	System	25 Aug 2020 04:34:35
	System	25 Aug 2020 04:34:35

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:20', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f57e6582-1f17-4d25-89c3-d99db962bffc' User entered 'None (0)'	System	25 Aug 2020 04:34:35
	System	25 Aug 2020 04:34:35

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:22', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f57e6582-1f17-4d25-89c3-d99db962bffc' User entered 'None (0)'	System	25 Aug 2020 04:34:35
	System	25 Aug 2020 04:34:35

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f57e6582-1f17-4d25-89c3-d99db962bffc'	System	25 Aug 2020 04:34:35
User entered 'No (N)'	System	25 Aug 2020 04:34:35

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-24T22:34:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f57e6582-1f17-4d25-89c3-d99db962bffc' User entered '24 Aug 2020 22:34'	System	25 Aug 2020 04:34:35
	System	25 Aug 2020 04:34:35

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Aug 2020 18:47'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 2'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:16', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2d63268c-65d8-45ab-b70d-d6caed6df3cc' User entered 'None (0)'	System	26 Aug 2020 01:51:38
	System	26 Aug 2020 01:51:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:19', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2d63268c-65d8-45ab-b70d-d6caed6df3cc' User entered 'None (0)'	System	26 Aug 2020 01:51:38
	System	26 Aug 2020 01:51:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:22', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2d63268c-65d8-45ab-b70d-d6caed6df3cc' User entered 'None (0)'	System	26 Aug 2020 01:51:38
	System	26 Aug 2020 01:51:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:25', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2d63268c-65d8-45ab-b70d-d6caed6df3cc' User entered 'None (0)'	System	26 Aug 2020 01:51:38
	System	26 Aug 2020 01:51:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:27', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2d63268c-65d8-45ab-b70d-d6caed6df3cc' User entered 'None (0)'	System	26 Aug 2020 01:51:38
	System	26 Aug 2020 01:51:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:29', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2d63268c-65d8-45ab-b70d-d6caed6df3cc' User entered 'None (0)'	System	26 Aug 2020 01:51:38
	System	26 Aug 2020 01:51:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:32', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2d63268c-65d8-45ab-b70d-d6caed6df3cc' User entered 'No (N)'	System	26 Aug 2020 01:51:38
	System	26 Aug 2020 01:51:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-25T19:51:36', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2d63268c-65d8-45ab-b70d-d6caed6df3cc' User entered '25 Aug 2020 19:51'	System	26 Aug 2020 01:51:38
	System	26 Aug 2020 01:51:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 3'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:58:22', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2af9249b-ba63-4669-b148-30547b1bb99b' User entered 'None (0)'	System	26 Aug 2020 18:59:47
	System	26 Aug 2020 18:59:47

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:58:24', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2af9249b-ba63-4669-b148-30547b1bb99b' User entered 'None (0)'	System	26 Aug 2020 18:59:47
	System	26 Aug 2020 18:59:47

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:58:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2af9249b-ba63-4669-b148-30547b1bb99b' User entered 'None (0)'	System	26 Aug 2020 18:59:47
	System	26 Aug 2020 18:59:47

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:58:29', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2af9249b-ba63-4669-b148-30547b1bb99b' User entered 'None (0)'	System	26 Aug 2020 18:59:47
	System	26 Aug 2020 18:59:47

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:58:31', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2af9249b-ba63-4669-b148-30547b1bb99b' User entered 'None (0)'	System	26 Aug 2020 18:59:47
	System	26 Aug 2020 18:59:47

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:58:34', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2af9249b-ba63-4669-b148-30547b1bb99b' User entered 'None (0)'	System	26 Aug 2020 18:59:47
	System	26 Aug 2020 18:59:47

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:58:37', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2af9249b-ba63-4669-b148-30547b1bb99b' User entered 'No (N)'	System	26 Aug 2020 18:59:47
	System	26 Aug 2020 18:59:47

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-26T12:59:04', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2af9249b-ba63-4669-b148-30547b1bb99b' User entered '26 Aug 2020 12:59'	System	26 Aug 2020 18:59:47
	System	26 Aug 2020 18:59:47

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 4'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:09', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '89d45ab7-4c59-4469-b782-0c1783d7277e' User entered 'None (0)'	System	28 Aug 2020 00:06:38
	System	28 Aug 2020 00:06:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:15', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '89d45ab7-4c59-4469-b782-0c1783d7277e'	System	28 Aug 2020 00:06:38
User entered 'Some interference with activity (2)'	System	28 Aug 2020 00:06:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:19', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '89d45ab7-4c59-4469-b782-0c1783d7277e'	System	28 Aug 2020 00:06:38
User entered 'Some interference with activity (2)'	System	28 Aug 2020 00:06:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:23', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '89d45ab7-4c59-4469-b782-0c1783d7277e' User entered 'None (0)'	System	28 Aug 2020 00:06:38
	System	28 Aug 2020 00:06:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:25', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '89d45ab7-4c59-4469-b782-0c1783d7277e' User entered 'None (0)'	System	28 Aug 2020 00:06:38
	System	28 Aug 2020 00:06:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:27', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '89d45ab7-4c59-4469-b782-0c1783d7277e' User entered 'None (0)'	System	28 Aug 2020 00:06:38
	System	28 Aug 2020 00:06:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '89d45ab7-4c59-4469-b782-0c1783d7277e' User entered 'No (N)'	System	28 Aug 2020 00:06:38
	System	28 Aug 2020 00:06:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-27T18:06:35', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '89d45ab7-4c59-4469-b782-0c1783d7277e' User entered '27 Aug 2020 18:06'	System	28 Aug 2020 00:06:38
	System	28 Aug 2020 00:06:38

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 5'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:38', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ddb745e-20fc-42f6-9d4c-cfac28dbdd23' User entered 'None (0)'	System	28 Aug 2020 20:15:05
	System	28 Aug 2020 20:15:05

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:42', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ddb745e-20fc-42f6-9d4c-cfac28dbdd23'	System	28 Aug 2020 20:15:05
User entered 'No interference with activity (1)'	System	28 Aug 2020 20:15:05

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:46', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ddb745e-20fc-42f6-9d4c-cfac28dbdd23' User entered 'None (0)'	System	28 Aug 2020 20:15:05
	System	28 Aug 2020 20:15:05

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:51', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ddb745e-20fc-42f6-9d4c-cfac28dbdd23'	System	28 Aug 2020 20:15:05
User entered 'Some interference with activity (2)'	System	28 Aug 2020 20:15:05

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:53', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ddb745e-20fc-42f6-9d4c-cfac28dbdd23' User entered 'None (0)'	System	28 Aug 2020 20:15:05
	System	28 Aug 2020 20:15:05

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:56', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ddb745e-20fc-42f6-9d4c-cfac28dbdd23' User entered 'None (0)'	System	28 Aug 2020 20:15:05
	System	28 Aug 2020 20:15:05

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:14:58', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ddb745e-20fc-42f6-9d4c-cfac28dbdd23'	System	28 Aug 2020 20:15:05
User entered 'No (N)'	System	28 Aug 2020 20:15:05

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-28T14:15:01', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ddb745e-20fc-42f6-9d4c-cfac28dbdd23' User entered '28 Aug 2020 14:15'	System	28 Aug 2020 20:15:05
	System	28 Aug 2020 20:15:05

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 6'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:31', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '73cf3f00-f114-42e8-af3a-728c575c943c' User entered 'None (0)'	System	29 Aug 2020 21:40:07
	System	29 Aug 2020 21:40:07

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:36', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '73cf3f00-f114-42e8-af3a-728c575c943c'	System	29 Aug 2020 21:40:07
User entered 'No interference with activity (1)'	System	29 Aug 2020 21:40:07

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:44', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '73cf3f00-f114-42e8-af3a-728c575c943c'	System	29 Aug 2020 21:40:07
User entered 'No interference with activity (1)'	System	29 Aug 2020 21:40:07

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:48', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '73cf3f00-f114-42e8-af3a-728c575c943c' User entered 'None (0)'	System	29 Aug 2020 21:40:07
	System	29 Aug 2020 21:40:07

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:51', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '73cf3f00-f114-42e8-af3a-728c575c943c' User entered 'None (0)'	System	29 Aug 2020 21:40:07
	System	29 Aug 2020 21:40:07

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:55', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '73cf3f00-f114-42e8-af3a-728c575c943c' User entered 'None (0)'	System	29 Aug 2020 21:40:07
	System	29 Aug 2020 21:40:07

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:39:58', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '73cf3f00-f114-42e8-af3a-728c575c943c' User entered 'No (N)'	System	29 Aug 2020 21:40:07
	System	29 Aug 2020 21:40:07

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-29T15:40:04', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '73cf3f00-f114-42e8-af3a-728c575c943c'	System	29 Aug 2020 21:40:07
User entered '29 Aug 2020 15:40'	System	29 Aug 2020 21:40:07

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 7'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:07', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '94575753-58a0-45db-96cc-698a97cc91fe' User entered 'None (0)'	System	31 Aug 2020 05:04:25
	System	31 Aug 2020 05:04:25

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:09', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '94575753-58a0-45db-96cc-698a97cc91fe' User entered 'None (0)'	System	31 Aug 2020 05:04:25
	System	31 Aug 2020 05:04:25

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:11', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '94575753-58a0-45db-96cc-698a97cc91fe' User entered 'None (0)'	System	31 Aug 2020 05:04:25
	System	31 Aug 2020 05:04:25

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:13', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '94575753-58a0-45db-96cc-698a97cc91fe' User entered 'None (0)'	System	31 Aug 2020 05:04:25
	System	31 Aug 2020 05:04:25

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:15', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '94575753-58a0-45db-96cc-698a97cc91fe' User entered 'None (0)'	System	31 Aug 2020 05:04:25
	System	31 Aug 2020 05:04:25

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:17', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '94575753-58a0-45db-96cc-698a97cc91fe' User entered 'None (0)'	System	31 Aug 2020 05:04:25
	System	31 Aug 2020 05:04:25

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:20', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '94575753-58a0-45db-96cc-698a97cc91fe' User entered 'No (N)'	System	31 Aug 2020 05:04:25
	System	31 Aug 2020 05:04:25

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-30T23:04:23', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '94575753-58a0-45db-96cc-698a97cc91fe' User entered '30 Aug 2020 23:04'	System	31 Aug 2020 05:04:25
	System	31 Aug 2020 05:04:25

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	29 Aug 2020 21:39:08
User entered 'Day 8'	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-31T12:59:45', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '7cc4c95e-e8c0-4955-bff0-fb0bebc9bdbc' User entered 'No (N)'	System	31 Aug 2020 18:59:52
	System	31 Aug 2020 18:59:52

US3332059

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-08-31T12:59:50', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '7cc4c95e-e8c0-4955-bff0-fb0bebc9bdbc' User entered '31 Aug 2020 12:59'	System	31 Aug 2020 18:59:52
	System	31 Aug 2020 18:59:52

US3332059

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 21:39:08

US3332059

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 21:39:08

US3332059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:41:20

US3332059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:41:20

US3332059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:41:20

US3332059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:41:20

US3332059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:41:24

US3332059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	02 Sep 2020 21:41:24

US3332059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Sep 2020 21:37:18

US3332059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '09 Sep 2020'	Ty Henry (b) (4)	16 Sep 2020 21:37:18

US3332059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	16 Sep 2020 21:37:18

US3332059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Ty Henry (b) (4)	16 Sep 2020 21:37:18

US3332059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Sep 2020 21:37:44

US3332059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	16 Sep 2020 21:37:44

US3332059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Sep 2020 21:38:43

US3332059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '15 Sep 2020'	Ty Henry (b) (4)	16 Sep 2020 21:38:43

US3332059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	16 Sep 2020 21:38:43

US3332059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Ty Henry (b) (4)	16 Sep 2020 21:38:43

US3332059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Sep 2020 21:39:42

US3332059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	16 Sep 2020 21:39:42

US3332059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	18 Sep 2020 21:30:52

US3332059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '18 Sep 2020'	Ty Henry (b) (4)	18 Sep 2020 21:30:52

US3332059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Clinic (Clinic)'	Ty Henry (b) (4)	18 Sep 2020 21:30:52

US3332059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'VISIT2'	System	18 Sep 2020 21:30:52

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User accepted default value 'Pre-Dose (PREDOSE)'	Ty Henry (b) (4) (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '18 Sep 2020'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13:30'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '18 Sep 2020 13:30'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '98.4' F	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Oral (Oral)'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '60'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'bpm'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '16'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'breaths/min'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '106'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '62'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User accepted default value 'Post-Dose (POSTDOSE)'	Ty Henry (b) (4) (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '18 Sep 2020'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '15:13'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '18 Sep 2020 15:13'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '99.2' F	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Oral (Oral)'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '55'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'bpm'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '16'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'breaths/min'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '105'	Ty Henry (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User closed query 'Previous query response indicates, "not an ae", however it was not indicated whether this was CS/NCS. Please clarify and update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:10:20
Query 'Previous query response indicates, "not an ae", however it was not indicated whether this was CS/NCS. Please clarify and update if appropriate.' answered with 'NCS' (Site from DM).	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:51:46
User opened query 'Previous query response indicates, "not an ae", however it was not indicated whether this was CS/NCS. Please clarify and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:06:28
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 13:06:23
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not an ae' (Site from System).	Colby Bostock (b) (4) (b) (4)	18 Sep 2020 23:37:13
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		18 Sep 2020 21:31:54
User entered '53'	Ty Henry (b) (4) (b) (4)	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	18 Sep 2020 21:31:54

US3332059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	18 Sep 2020 21:32:30

US3332059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '18 Sep 2020'	Ty Henry (b) (4)	18 Sep 2020 21:32:30

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Megan Grimmatt (b) (4)	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Megan Grimmatt (b) (4)	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Megan Grimmatt (b) (4)	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '18 Sep 2020'	Megan Grimmatt (b) (4)	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '14:42'	Megan Grimmatt (b) (4)	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '18 Sep 2020 14:42'	System	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Left Arm (LEFT ARM)'	Megan Grimmatt (b) (4)	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'ONCE'	System	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 21:02:03

US3332059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	18 Sep 2020 21:32:55

US3332059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '18 Sep 2020'	Ty Henry (b) (4)	18 Sep 2020 21:32:55

US3332059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13:45'	Ty Henry (b) (4)	18 Sep 2020 21:32:55

US3332059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '18 Sep 2020 13:45'	System	18 Sep 2020 21:32:55

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '18 Sep 2020'	Ty Henry (b) (4)	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Ty Henry (b) (4) (b) (4)	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13:42'	Ty Henry (b) (4)	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '18 Sep 2020 13:42'	System	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Ty Henry (b) (4) (b) (4)	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'No (N)'	Ty Henry (b) (4)	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Ty Henry (b) (4)	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered empty.	System	18 Sep 2020 21:33:09

US3332059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	18 Sep 2020 21:33:15

US3332059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	18 Sep 2020 21:33:15

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:10', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '416af7ae-b347-4526-9046-ce67873a06b0' User entered 'Yes (Y)'	System	18 Sep 2020 21:15:27
	System	18 Sep 2020 21:15:27

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:16', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '416af7ae-b347-4526-9046-ce67873a06b0' User entered '99.3'	System	18 Sep 2020 21:15:27
	System	18 Sep 2020 21:15:27

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:19', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '416af7ae-b347-4526-9046-ce67873a06b0' User entered 'No (N)'	System	18 Sep 2020 21:15:27
	System	18 Sep 2020 21:15:27

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:23', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '416af7ae-b347-4526-9046-ce67873a06b0' User entered '18 Sep 2020 15:15'	System	18 Sep 2020 21:15:27
	System	18 Sep 2020 21:15:27

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '18 Sep 2020 15:02'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '18 Sep 2020 17:32'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dee1e1c7-113a-4896-b26d-0d604d46b522'	System	19 Sep 2020 03:12:43
User entered 'Yes (Y)'	System	19 Sep 2020 03:12:43

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:31', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dee1e1c7-113a-4896-b26d-0d604d46b522'	System	19 Sep 2020 03:12:43
User entered '97.4'	System	19 Sep 2020 03:12:43

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:36', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dee1e1c7-113a-4896-b26d-0d604d46b522'	System	19 Sep 2020 03:12:43
User entered 'No (N)'	System	19 Sep 2020 03:12:43

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dee1e1c7-113a-4896-b26d-0d604d46b522'	System	19 Sep 2020 03:12:43
User entered '18 Sep 2020 21:12'	System	19 Sep 2020 03:12:43

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '18 Sep 2020 18:27'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 2'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:04:25', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '09ca38cf-47bd-4266-bf1e-eadd1ab10fb8' User entered 'Yes (Y)'	System	19 Sep 2020 18:04:48
	System	19 Sep 2020 18:04:48

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:04:31', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '09ca38cf-47bd-4266-bf1e-eadd1ab10fb8' User entered '98.8'	System	19 Sep 2020 18:04:48
	System	19 Sep 2020 18:04:48

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:04:34', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '09ca38cf-47bd-4266-bf1e-eadd1ab10fb8' User entered 'Yes (Y)'	System	19 Sep 2020 18:04:48
	System	19 Sep 2020 18:04:48

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data to be updated as appropriate.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 06:22:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Ty Henry (b) (4)	23 Sep 2020 16:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:04:38', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '09ca38cf-47bd-4266-bf1e-eadd1ab10fb8'	(b) (4)	
User entered '1'	System	19 Sep 2020 18:04:48
	System	19 Sep 2020 18:04:48
	System	19 Sep 2020 18:04:48

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:04:38', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '09ca38cf-47bd-4266-bf1e-eadd1ab10fb8' User entered '0'	System	19 Sep 2020 18:04:48
	System	19 Sep 2020 18:04:48

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:04:46', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '09ca38cf-47bd-4266-bf1e-eadd1ab10fb8' User entered '19 Sep 2020 12:04'	System	19 Sep 2020 18:04:48
	System	19 Sep 2020 18:04:48

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 3'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:11', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '81fe8f54-7a7a-4ba7-88e0-acafae7b774'	System	20 Sep 2020 19:56:28
User entered 'Yes (Y)'	System	20 Sep 2020 19:56:28

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:20', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '81fe8f54-7a7a-4ba7-88e0-acafae7b774' User entered '97.8'	System	20 Sep 2020 19:56:28
	System	20 Sep 2020 19:56:28

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:24', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '81fe8f54-7a7a-4ba7-88e0-acafae7b774'	System	20 Sep 2020 19:56:28
User entered 'No (N)'	System	20 Sep 2020 19:56:28

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:27', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '81fe8f54-7a7a-4ba7-88e0-acafae7b774'	System	20 Sep 2020 19:56:28
User entered '20 Sep 2020 13:56'	System	20 Sep 2020 19:56:28

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 4'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:42:55', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '548b5f76-4f33-413c-9781-d58d2e188f5e' User entered 'Yes (Y)'	System	21 Sep 2020 18:43:09
	System	21 Sep 2020 18:43:09

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:01', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '548b5f76-4f33-413c-9781-d58d2e188f5e' User entered '97.7'	System	21 Sep 2020 18:43:09
	System	21 Sep 2020 18:43:09

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:03', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '548b5f76-4f33-413c-9781-d58d2e188f5e' User entered 'No (N)'	System	21 Sep 2020 18:43:09
	System	21 Sep 2020 18:43:09

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:06', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '548b5f76-4f33-413c-9781-d58d2e188f5e' User entered '21 Sep 2020 12:43'	System	21 Sep 2020 18:43:09
	System	21 Sep 2020 18:43:09

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 5'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:11:56', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '06e6e1b4-752e-42b8-b0c8-13008bc47367' User entered 'No (N)'	System	23 Sep 2020 14:12:06
	System	23 Sep 2020 14:12:06

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:11:59', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '06e6e1b4-752e-42b8-b0c8-13008bc47367' User entered 'No (N)'	System	23 Sep 2020 14:12:06
	System	23 Sep 2020 14:12:06

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:02', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '06e6e1b4-752e-42b8-b0c8-13008bc47367' User entered '23 Sep 2020 08:12'	System	23 Sep 2020 14:12:06
	System	23 Sep 2020 14:12:06

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 6'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:30:43', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '74066e6c-6ca5-4b36-8633-3cdfb3f81acd' User entered 'Yes (Y)'	System	23 Sep 2020 18:35:05
	System	23 Sep 2020 18:35:05

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:30:48', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '74066e6c-6ca5-4b36-8633-3cdfb3f81acd' User entered '97.6'	System	23 Sep 2020 18:35:05
	System	23 Sep 2020 18:35:05

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:30:51', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '74066e6c-6ca5-4b36-8633-3cdfb3f81acd' User entered 'No (N)'	System	23 Sep 2020 18:35:05
	System	23 Sep 2020 18:35:05

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:30:53', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '74066e6c-6ca5-4b36-8633-3cdfb3f81acd' User entered '23 Sep 2020 12:30'	System	23 Sep 2020 18:35:05
	System	23 Sep 2020 18:35:05

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 7'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:42:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e6bb2f46-abe2-42ef-84b9-00ccd99d8691' User entered 'Yes (Y)'	System	24 Sep 2020 18:42:53
	System	24 Sep 2020 18:42:53

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:42:45', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e6bb2f46-abe2-42ef-84b9-00ccd99d8691' User entered '97.9'	System	24 Sep 2020 18:42:53
	System	24 Sep 2020 18:42:53

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:42:48', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e6bb2f46-abe2-42ef-84b9-00ccd99d8691' User entered 'No (N)'	System	24 Sep 2020 18:42:53
	System	24 Sep 2020 18:42:53

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:42:51', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e6bb2f46-abe2-42ef-84b9-00ccd99d8691' User entered '24 Sep 2020 12:42'	System	24 Sep 2020 18:42:53
	System	24 Sep 2020 18:42:53

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '269a5204-d8b3-42b5-b389-5eecfe5c9017'	System	18 Sep 2020 21:16:08
User entered 'None (1)'	System	18 Sep 2020 21:16:08

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:49', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '269a5204-d8b3-42b5-b389-5eecfe5c9017' User entered 'No (N)'	System	18 Sep 2020 21:16:08
	System	18 Sep 2020 21:16:08

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:52', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '269a5204-d8b3-42b5-b389-5eecfe5c9017' User entered 'No (N)'	System	18 Sep 2020 21:16:08
	System	18 Sep 2020 21:16:08

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:56', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '269a5204-d8b3-42b5-b389-5eecfe5c9017' User entered 'None (1)'	System	18 Sep 2020 21:16:08
	System	18 Sep 2020 21:16:08

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:15:59', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '269a5204-d8b3-42b5-b389-5eecfe5c9017' User entered '18 Sep 2020 15:15'	System	18 Sep 2020 21:16:08
	System	18 Sep 2020 21:16:08

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '18 Sep 2020 15:02'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '18 Sep 2020 17:32'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:11:03', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71a5ae7a-9080-444d-9555-ce91a99b1d52'	System	19 Sep 2020 03:12:25
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 03:12:25

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:11:27', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71a5ae7a-9080-444d-9555-ce91a99b1d52'	System	19 Sep 2020 03:12:25
User entered 'No (N)'	System	19 Sep 2020 03:12:25

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:11:42', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71a5ae7a-9080-444d-9555-ce91a99b1d52'	System	19 Sep 2020 03:12:25
User entered 'Yes (Y)'	System	19 Sep 2020 03:12:25

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:06', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71a5ae7a-9080-444d-9555-ce91a99b1d52' User entered '25'	System	19 Sep 2020 03:12:25
	System	19 Sep 2020 03:12:25

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:10', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71a5ae7a-9080-444d-9555-ce91a99b1d52'	System	19 Sep 2020 03:12:25
User entered 'None (1)'	System	19 Sep 2020 03:12:25

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:20', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71a5ae7a-9080-444d-9555-ce91a99b1d52'	System	19 Sep 2020 03:12:25
User entered '18 Sep 2020 21:12'	System	19 Sep 2020 03:12:25

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '18 Sep 2020 18:27'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 2'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'severity rating refers to subject either taking a CM OR the interference with activity. correct as entered ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:11:07
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'severity rating refers to subject either taking a CM OR the interference with activity. correct as entered ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:37:59
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:38:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:05:19', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0f30141b-e881-42e6-b774-0f8de26312d0'	System	19 Sep 2020 18:05:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	19 Sep 2020 18:05:52

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:05:22', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0f30141b-e881-42e6-b774-0f8de26312d0' User entered 'No (N)'	System	19 Sep 2020 18:05:52
	System	19 Sep 2020 18:05:52

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:05:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0f30141b-e881-42e6-b774-0f8de26312d0' User entered 'Yes (Y)'	System	19 Sep 2020 18:05:52
	System	19 Sep 2020 18:05:52

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:05:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0f30141b-e881-42e6-b774-0f8de26312d0' User entered '25'	System	19 Sep 2020 18:05:52
	System	19 Sep 2020 18:05:52

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:05:44', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0f30141b-e881-42e6-b774-0f8de26312d0' User entered 'None (1)'	System	19 Sep 2020 18:05:52
	System	19 Sep 2020 18:05:52

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:05:50', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0f30141b-e881-42e6-b774-0f8de26312d0' User entered '19 Sep 2020 12:05'	System	19 Sep 2020 18:05:52
	System	19 Sep 2020 18:05:52

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 3'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '72a9dfa9-1df9-462a-9efb-b4f557250945'	System	20 Sep 2020 19:56:48
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 19:56:48

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:36', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '72a9dfa9-1df9-462a-9efb-b4f557250945'	System	20 Sep 2020 19:56:48
User entered 'No (N)'	System	20 Sep 2020 19:56:48

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:38', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '72a9dfa9-1df9-462a-9efb-b4f557250945'	System	20 Sep 2020 19:56:48
User entered 'No (N)'	System	20 Sep 2020 19:56:48

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:41', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '72a9dfa9-1df9-462a-9efb-b4f557250945'	System	20 Sep 2020 19:56:48
User entered 'None (1)'	System	20 Sep 2020 19:56:48

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:45', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '72a9dfa9-1df9-462a-9efb-b4f557250945'	System	20 Sep 2020 19:56:48
User entered '20 Sep 2020 13:56'	System	20 Sep 2020 19:56:48

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 4'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:12', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68d9c2fb-9657-49fb-afe6-ef81e36e03c5'	System	21 Sep 2020 18:43:24
User entered 'None (1)'	System	21 Sep 2020 18:43:24

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:15', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68d9c2fb-9657-49fb-afe6-ef81e36e03c5'	System	21 Sep 2020 18:43:24
User entered 'No (N)'	System	21 Sep 2020 18:43:24

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:17', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68d9c2fb-9657-49fb-afe6-ef81e36e03c5'	System	21 Sep 2020 18:43:24
User entered 'No (N)'	System	21 Sep 2020 18:43:24

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:20', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68d9c2fb-9657-49fb-afe6-ef81e36e03c5'	System	21 Sep 2020 18:43:24
User entered 'None (1)'	System	21 Sep 2020 18:43:24

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:23', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '68d9c2fb-9657-49fb-afe6-ef81e36e03c5'	System	21 Sep 2020 18:43:24
User entered '21 Sep 2020 12:43'	System	21 Sep 2020 18:43:24

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 5'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:06', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0e596e6d-eab1-4297-aad4-4d830ee05fed' User entered 'None (1)'	System	23 Sep 2020 14:12:19
	System	23 Sep 2020 14:12:19

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:09', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0e596e6d-eab1-4297-aad4-4d830ee05fed' User entered 'No (N)'	System	23 Sep 2020 14:12:19
	System	23 Sep 2020 14:12:19

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:11', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0e596e6d-eab1-4297-aad4-4d830ee05fed' User entered 'No (N)'	System	23 Sep 2020 14:12:19
	System	23 Sep 2020 14:12:19

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:13', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0e596e6d-eab1-4297-aad4-4d830ee05fed' User entered 'None (1)'	System	23 Sep 2020 14:12:19
	System	23 Sep 2020 14:12:19

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:18', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '0e596e6d-eab1-4297-aad4-4d830ee05fed' User entered '23 Sep 2020 08:12'	System	23 Sep 2020 14:12:19
	System	23 Sep 2020 14:12:19

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 6'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:30:57', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd4aeffb1-4ec6-4fac-b655-4bd1daceb0d3'	System	23 Sep 2020 18:35:37
User entered 'None (1)'	System	23 Sep 2020 18:35:37

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:30:59', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd4aeffb1-4ec6-4fac-b655-4bd1daceb0d3' User entered 'No (N)'	System	23 Sep 2020 18:35:37
	System	23 Sep 2020 18:35:37

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:02', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd4aeffb1-4ec6-4fac-b655-4bd1daceb0d3' User entered 'No (N)'	System	23 Sep 2020 18:35:37
	System	23 Sep 2020 18:35:37

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:04', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd4aeffb1-4ec6-4fac-b655-4bd1daceb0d3'	System	23 Sep 2020 18:35:37
User entered 'None (1)'	System	23 Sep 2020 18:35:37

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:07', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd4aeffb1-4ec6-4fac-b655-4bd1daceb0d3' User entered '23 Sep 2020 12:31'	System	23 Sep 2020 18:35:37
	System	23 Sep 2020 18:35:37

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 7'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:42:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1332f866-5fcb-496d-a272-5ad7967ef5d9'	System	24 Sep 2020 18:43:06
User entered 'None (1)'	System	24 Sep 2020 18:43:06

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:42:56', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1332f866-5fcb-496d-a272-5ad7967ef5d9' User entered 'No (N)'	System	24 Sep 2020 18:43:06
	System	24 Sep 2020 18:43:06

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:42:58', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1332f866-5fcb-496d-a272-5ad7967ef5d9' User entered 'No (N)'	System	24 Sep 2020 18:43:06
	System	24 Sep 2020 18:43:06

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:01', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1332f866-5fcb-496d-a272-5ad7967ef5d9'	System	24 Sep 2020 18:43:06
User entered 'None (1)'	System	24 Sep 2020 18:43:06

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:03', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1332f866-5fcb-496d-a272-5ad7967ef5d9' User entered '24 Sep 2020 12:43'	System	24 Sep 2020 18:43:06
	System	24 Sep 2020 18:43:06

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:54:04
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:16:03', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'c6a403cf-da1d-4414-b325-414c47af5257' User entered 'None (0)'	System	18 Sep 2020 21:16:38
	System	18 Sep 2020 21:16:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:16:06', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'c6a403cf-da1d-4414-b325-414c47af5257' User entered 'None (0)'	System	18 Sep 2020 21:16:38
	System	18 Sep 2020 21:16:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:16:11', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'c6a403cf-da1d-4414-b325-414c47af5257' User entered 'None (0)'	System	18 Sep 2020 21:16:38
	System	18 Sep 2020 21:16:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:16:14', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'c6a403cf-da1d-4414-b325-414c47af5257' User entered 'None (0)'	System	18 Sep 2020 21:16:38
	System	18 Sep 2020 21:16:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:16:16', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'c6a403cf-da1d-4414-b325-414c47af5257' User entered 'None (0)'	System	18 Sep 2020 21:16:38
	System	18 Sep 2020 21:16:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:16:19', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'c6a403cf-da1d-4414-b325-414c47af5257' User entered 'None (0)'	System	18 Sep 2020 21:16:38
	System	18 Sep 2020 21:16:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:16:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'c6a403cf-da1d-4414-b325-414c47af5257' User entered 'No (N)'	System	18 Sep 2020 21:16:38
	System	18 Sep 2020 21:16:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T15:16:36', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'c6a403cf-da1d-4414-b325-414c47af5257' User entered '18 Sep 2020 15:16'	System	18 Sep 2020 21:16:38
	System	18 Sep 2020 21:16:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '18 Sep 2020 15:02'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '18 Sep 2020 17:32'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:49', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'a5eacdd3-f03f-4a7e-96a7-fc740507740a'	System	19 Sep 2020 03:13:21
User entered 'No interference with activity (1)'	System	19 Sep 2020 03:13:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:12:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'a5eacdd3-f03f-4a7e-96a7-fc740507740a'	System	19 Sep 2020 03:13:21
User entered 'No interference with activity (1)'	System	19 Sep 2020 03:13:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:13:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'a5eacdd3-f03f-4a7e-96a7-fc740507740a' User entered 'No interference with activity (1)'	System	19 Sep 2020 03:13:21
	System	19 Sep 2020 03:13:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:13:04', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'a5eacdd3-f03f-4a7e-96a7-fc740507740a' User entered 'None (0)'	System	19 Sep 2020 03:13:21
	System	19 Sep 2020 03:13:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:13:07', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'a5eacdd3-f03f-4a7e-96a7-fc740507740a' User entered 'None (0)'	System	19 Sep 2020 03:13:21
	System	19 Sep 2020 03:13:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:13:10', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'a5eacdd3-f03f-4a7e-96a7-fc740507740a' User entered 'None (0)'	System	19 Sep 2020 03:13:21
	System	19 Sep 2020 03:13:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:13:13', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'a5eacdd3-f03f-4a7e-96a7-fc740507740a' User entered 'No (N)'	System	19 Sep 2020 03:13:21
	System	19 Sep 2020 03:13:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-18T21:13:19', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'a5eacdd3-f03f-4a7e-96a7-fc740507740a' User entered '18 Sep 2020 21:13'	System	19 Sep 2020 03:13:21
	System	19 Sep 2020 03:13:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '18 Sep 2020 18:27'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 2'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:06:01', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71cdea54-2bf0-4f77-8bc2-5006f3f64cb7'	System	19 Sep 2020 18:06:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Sep 2020 18:06:57

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:06:07', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71cdea54-2bf0-4f77-8bc2-5006f3f64cb7'	System	19 Sep 2020 18:06:57
User entered 'Significant; prevents daily activity (3)'	System	19 Sep 2020 18:06:57

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:06:11', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71cdea54-2bf0-4f77-8bc2-5006f3f64cb7'	System	19 Sep 2020 18:06:57
User entered 'Significant; prevents daily activity (3)'	System	19 Sep 2020 18:06:57

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:06:18', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71cdea54-2bf0-4f77-8bc2-5006f3f64cb7'	System	19 Sep 2020 18:06:57
User entered 'Some interference with activity (2)'	System	19 Sep 2020 18:06:57

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:06:32', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71cdea54-2bf0-4f77-8bc2-5006f3f64cb7'	System	19 Sep 2020 18:06:57
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Sep 2020 18:06:57

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:06:42', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71cdea54-2bf0-4f77-8bc2-5006f3f64cb7'	System	19 Sep 2020 18:06:57
User entered 'Some interference with activity not requiring medical attention (2)'	System	19 Sep 2020 18:06:57

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:06:47', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71cdea54-2bf0-4f77-8bc2-5006f3f64cb7' User entered 'No (N)'	System	19 Sep 2020 18:06:57
	System	19 Sep 2020 18:06:57

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-19T12:06:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '71cdea54-2bf0-4f77-8bc2-5006f3f64cb7' User entered '19 Sep 2020 12:06'	System	19 Sep 2020 18:06:57
	System	19 Sep 2020 18:06:57

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 3'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:50', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3240ab5e-6202-4c37-9cd9-4350aa71a427' User entered 'None (0)'	System	20 Sep 2020 19:57:21
	System	20 Sep 2020 19:57:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3240ab5e-6202-4c37-9cd9-4350aa71a427'	System	20 Sep 2020 19:57:21
User entered 'Some interference with activity (2)'	System	20 Sep 2020 19:57:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:56:58', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3240ab5e-6202-4c37-9cd9-4350aa71a427'	System	20 Sep 2020 19:57:21
User entered 'No interference with activity (1)'	System	20 Sep 2020 19:57:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:57:01', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3240ab5e-6202-4c37-9cd9-4350aa71a427' User entered 'None (0)'	System	20 Sep 2020 19:57:21
	System	20 Sep 2020 19:57:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:57:03', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3240ab5e-6202-4c37-9cd9-4350aa71a427' User entered 'None (0)'	System	20 Sep 2020 19:57:21
	System	20 Sep 2020 19:57:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:57:06', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3240ab5e-6202-4c37-9cd9-4350aa71a427' User entered 'None (0)'	System	20 Sep 2020 19:57:21
	System	20 Sep 2020 19:57:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:57:11', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3240ab5e-6202-4c37-9cd9-4350aa71a427' User entered 'No (N)'	System	20 Sep 2020 19:57:21
	System	20 Sep 2020 19:57:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-20T13:57:16', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3240ab5e-6202-4c37-9cd9-4350aa71a427' User entered '20 Sep 2020 13:57'	System	20 Sep 2020 19:57:21
	System	20 Sep 2020 19:57:21

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 4'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd0f9470d-ae43-4ce6-abb5-898d53a7393e' User entered 'None (0)'	System	21 Sep 2020 18:43:44
	System	21 Sep 2020 18:43:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:29', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd0f9470d-ae43-4ce6-abb5-898d53a7393e' User entered 'None (0)'	System	21 Sep 2020 18:43:44
	System	21 Sep 2020 18:43:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:30', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd0f9470d-ae43-4ce6-abb5-898d53a7393e' User entered 'None (0)'	System	21 Sep 2020 18:43:44
	System	21 Sep 2020 18:43:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd0f9470d-ae43-4ce6-abb5-898d53a7393e' User entered 'None (0)'	System	21 Sep 2020 18:43:44
	System	21 Sep 2020 18:43:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:35', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd0f9470d-ae43-4ce6-abb5-898d53a7393e' User entered 'None (0)'	System	21 Sep 2020 18:43:44
	System	21 Sep 2020 18:43:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:37', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd0f9470d-ae43-4ce6-abb5-898d53a7393e' User entered 'None (0)'	System	21 Sep 2020 18:43:44
	System	21 Sep 2020 18:43:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd0f9470d-ae43-4ce6-abb5-898d53a7393e' User entered 'No (N)'	System	21 Sep 2020 18:43:44
	System	21 Sep 2020 18:43:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-21T12:43:42', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'd0f9470d-ae43-4ce6-abb5-898d53a7393e' User entered '21 Sep 2020 12:43'	System	21 Sep 2020 18:43:44
	System	21 Sep 2020 18:43:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 5'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:22', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b56f9e59-b7a6-48a6-9575-e36f22f9c17d' User entered 'None (0)'	System	23 Sep 2020 14:12:44
	System	23 Sep 2020 14:12:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b56f9e59-b7a6-48a6-9575-e36f22f9c17d'	System	23 Sep 2020 14:12:44
User entered 'Some interference with activity (2)'	System	23 Sep 2020 14:12:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:29', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b56f9e59-b7a6-48a6-9575-e36f22f9c17d' User entered 'None (0)'	System	23 Sep 2020 14:12:44
	System	23 Sep 2020 14:12:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:31', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b56f9e59-b7a6-48a6-9575-e36f22f9c17d' User entered 'None (0)'	System	23 Sep 2020 14:12:44
	System	23 Sep 2020 14:12:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:34', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b56f9e59-b7a6-48a6-9575-e36f22f9c17d' User entered 'None (0)'	System	23 Sep 2020 14:12:44
	System	23 Sep 2020 14:12:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:37', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b56f9e59-b7a6-48a6-9575-e36f22f9c17d' User entered 'None (0)'	System	23 Sep 2020 14:12:44
	System	23 Sep 2020 14:12:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:39', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b56f9e59-b7a6-48a6-9575-e36f22f9c17d' User entered 'No (N)'	System	23 Sep 2020 14:12:44
	System	23 Sep 2020 14:12:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T08:12:42', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'b56f9e59-b7a6-48a6-9575-e36f22f9c17d' User entered '23 Sep 2020 08:12'	System	23 Sep 2020 14:12:44
	System	23 Sep 2020 14:12:44

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 6'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:14', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ca77ccf7-768a-4c3a-96b1-e2d624c24e16'	System	23 Sep 2020 18:35:38
User entered 'No interference with activity (1)'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:17', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ca77ccf7-768a-4c3a-96b1-e2d624c24e16'	System	23 Sep 2020 18:35:38
User entered 'Some interference with activity (2)'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:20', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ca77ccf7-768a-4c3a-96b1-e2d624c24e16' User entered 'None (0)'	System	23 Sep 2020 18:35:38
	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:22', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ca77ccf7-768a-4c3a-96b1-e2d624c24e16' User entered 'None (0)'	System	23 Sep 2020 18:35:38
	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:24', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ca77ccf7-768a-4c3a-96b1-e2d624c24e16' User entered 'None (0)'	System	23 Sep 2020 18:35:38
	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:27', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ca77ccf7-768a-4c3a-96b1-e2d624c24e16' User entered 'None (0)'	System	23 Sep 2020 18:35:38
	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:30', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ca77ccf7-768a-4c3a-96b1-e2d624c24e16'	System	23 Sep 2020 18:35:38
User entered 'No (N)'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-23T12:31:32', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ca77ccf7-768a-4c3a-96b1-e2d624c24e16' User entered '23 Sep 2020 12:31'	System	23 Sep 2020 18:35:38
	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	18 Sep 2020 21:02:03
User entered 'Day 7'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:08', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '988fcdc7-1e24-4f88-b9a0-df5cb1781206' User entered 'None (0)'	System	24 Sep 2020 18:43:28
	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:10', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '988fcdc7-1e24-4f88-b9a0-df5cb1781206'	System	24 Sep 2020 18:43:28
User entered 'Some interference with activity (2)'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:13', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '988fcdc7-1e24-4f88-b9a0-df5cb1781206' User entered 'None (0)'	System	24 Sep 2020 18:43:28
	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:15', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '988fcdc7-1e24-4f88-b9a0-df5cb1781206' User entered 'None (0)'	System	24 Sep 2020 18:43:28
	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:17', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '988fcdc7-1e24-4f88-b9a0-df5cb1781206' User entered 'None (0)'	System	24 Sep 2020 18:43:28
	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:19', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '988fc7-1e24-4f88-b9a0-df5cb1781206'	System	24 Sep 2020 18:43:28
User entered 'None (0)'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:22', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '988fcdc7-1e24-4f88-b9a0-df5cb1781206' User entered 'No (N)'	System	24 Sep 2020 18:43:28
	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-24T12:43:24', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '988fcdc7-1e24-4f88-b9a0-df5cb1781206'	System	24 Sep 2020 18:43:28
User entered '24 Sep 2020 12:43'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:02:03

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	23 Sep 2020 18:35:38
User entered 'Day 8'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-25T13:59:58', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '18e33165-6360-4076-aad9-1e3cf9fac8df'	System	25 Sep 2020 20:00:08
User entered 'Some interference with activity (2)'	System	25 Sep 2020 20:00:08

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-25T14:00:01', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '18e33165-6360-4076-aad9-1e3cf9fac8df' User entered '25 Sep 2020 14:00'	System	25 Sep 2020 20:00:08
	System	25 Sep 2020 20:00:08

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Sep 2020 18:43:28
User entered 'Day 9'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-26T16:27:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '14656b8b-70e2-4f03-95b4-7d4bde76f7aa'	System	26 Sep 2020 22:27:59
User entered 'Some interference with activity (2)'	System	26 Sep 2020 22:27:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-26T16:27:57', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '14656b8b-70e2-4f03-95b4-7d4bde76f7aa'	System	26 Sep 2020 22:27:59
User entered '26 Sep 2020 16:27'	System	26 Sep 2020 22:27:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	25 Sep 2020 20:00:08
User entered 'Day 10'	System	25 Sep 2020 20:00:08

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-27T14:11:46', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '8983f357-9f5f-464c-b5b7-ce42d7e688f6'	System	27 Sep 2020 20:11:51
User entered 'Some interference with activity (2)'	System	27 Sep 2020 20:11:51

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-27T14:11:49', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '8983f357-9f5f-464c-b5b7-ce42d7e688f6' User entered '27 Sep 2020 14:11'	System	27 Sep 2020 20:11:51
	System	27 Sep 2020 20:11:51

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 20:00:08

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 20:00:08

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	26 Sep 2020 22:27:59
User entered 'Day 11'	System	26 Sep 2020 22:27:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-28T18:31:48', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '38d4e868-b018-4016-a3fb-813b1029c1c7'	System	29 Sep 2020 00:31:56
User entered 'Some interference with activity (2)'	System	29 Sep 2020 00:31:56

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-28T18:31:50', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '38d4e868-b018-4016-a3fb-813b1029c1c7'	System	29 Sep 2020 00:31:56
User entered '28 Sep 2020 18:31'	System	29 Sep 2020 00:31:56

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 22:27:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 22:27:59

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	27 Sep 2020 20:11:51
User entered 'Day 12'	System	27 Sep 2020 20:11:51

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-29T13:15:26', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '86bf1157-5371-4f59-8934-33745b1bd391' User entered 'None (0)'	System	29 Sep 2020 19:15:32
	System	29 Sep 2020 19:15:32

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-29T13:15:29', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '86bf1157-5371-4f59-8934-33745b1bd391' User entered '29 Sep 2020 13:15'	System	29 Sep 2020 19:15:32
	System	29 Sep 2020 19:15:32

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 20:11:51

US3332059

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 20:11:51

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	23 Sep 2020 18:35:38
User entered 'Day 8'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-25T14:00:06', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2cb104ab-e7e7-4039-ba11-8bb2981dd0ea' User entered 'No (N)'	System	25 Sep 2020 20:00:13
	System	25 Sep 2020 20:00:13

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-25T14:00:09', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2cb104ab-e7e7-4039-ba11-8bb2981dd0ea' User entered '25 Sep 2020 14:00'	System	25 Sep 2020 20:00:13
	System	25 Sep 2020 20:00:13

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:35:38

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Sep 2020 18:43:28
User entered 'Day 9'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-26T16:28:01', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '973fa482-6f7d-4f1e-996c-d38456a7958c' User entered 'No (N)'	System	26 Sep 2020 22:28:05
	System	26 Sep 2020 22:28:05

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-26T16:28:04', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '973fa482-6f7d-4f1e-996c-d38456a7958c'	System	26 Sep 2020 22:28:05
User entered '26 Sep 2020 16:28'	System	26 Sep 2020 22:28:05

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 18:43:28

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	25 Sep 2020 20:00:08
User entered 'Day 10'	System	25 Sep 2020 20:00:08

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-27T14:11:53', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '9d6890f2-30fa-4636-87f3-1dfa550c0392'	System	27 Sep 2020 20:11:59
User entered 'No (N)'	System	27 Sep 2020 20:11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-27T14:11:55', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '9d6890f2-30fa-4636-87f3-1dfa550c0392'	System	27 Sep 2020 20:11:59
User entered '27 Sep 2020 14:11'	System	27 Sep 2020 20:11:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 20:00:08

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 20:00:08

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	26 Sep 2020 22:27:59
User entered 'Day 11'	System	26 Sep 2020 22:27:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-28T18:31:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '28272e0b-01ed-4c2f-b733-5638e59e23db' User entered 'No (N)'	System	29 Sep 2020 00:31:58
	System	29 Sep 2020 00:31:58

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-28T18:31:57', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '28272e0b-01ed-4c2f-b733-5638e59e23db' User entered '28 Sep 2020 18:31'	System	29 Sep 2020 00:31:58
	System	29 Sep 2020 00:31:58

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 22:27:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 22:27:59

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	27 Sep 2020 20:11:51
User entered 'Day 12'	System	27 Sep 2020 20:11:51

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-29T13:15:32', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '8234c22d-624f-4687-9c77-2fae63992421' User entered 'No (N)'	System	29 Sep 2020 19:15:40
	System	29 Sep 2020 19:15:40

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-09-29T13:15:35', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '8234c22d-624f-4687-9c77-2fae63992421' User entered '29 Sep 2020 13:15'	System	29 Sep 2020 19:15:40
	System	29 Sep 2020 19:15:40

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 20:11:51

US3332059

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 20:11:51

US3332059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	28 Sep 2020 20:22:01

US3332059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '26 Sep 2020'	Ty Henry (b) (4)	28 Sep 2020 20:22:01

US3332059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	28 Sep 2020 20:22:01

US3332059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Ty Henry (b) (4)	28 Sep 2020 20:22:01

US3332059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	28 Sep 2020 20:22:09

US3332059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	28 Sep 2020 20:22:09

US3332059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	05 Oct 2020 17:31:37

US3332059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '04 Oct 2020'	Ty Henry (b) (4)	05 Oct 2020 17:31:37

US3332059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	05 Oct 2020 17:31:37

US3332059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Ty Henry (b) (4)	05 Oct 2020 17:31:37

US3332059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	05 Oct 2020 17:32:18

US3332059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	05 Oct 2020 17:32:18

US3332059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	13 Oct 2020 15:46:08

US3332059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '10 Oct 2020'	Ty Henry (b) (4)	13 Oct 2020 15:46:08

US3332059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	13 Oct 2020 15:46:08

US3332059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	Ty Henry (b) (4)	13 Oct 2020 15:46:08

US3332059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	13 Oct 2020 15:46:14

US3332059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	13 Oct 2020 15:46:14

US3332059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	13 Oct 2020 20:01:09

US3332059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13 Oct 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Oct 2020 20:01:09

US3332059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Clinic (Clinic)'	Ashley Bragg (b) (4)	13 Oct 2020 20:01:09

US3332059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'VISIT3'	System	13 Oct 2020 20:01:09

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13 Oct 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13:25'	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '13 Oct 2020 13:25'	System	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '98.0' F	Ashley Bragg (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Oral (Oral)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '65'	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'bpm'	System	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '16'	Ashley Bragg (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'breaths/min'	System	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '108'	Ashley Bragg (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '64'	Ashley Bragg (b) (4)	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'mmHg'	System	13 Oct 2020 20:01:49

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09

US3332059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09

US3332059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	13 Oct 2020 20:01:55

US3332059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13 Oct 2020'	Ashley Bragg (b) (4)	13 Oct 2020 20:01:55

US3332059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	13 Oct 2020 20:02:30

US3332059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13 Oct 2020'	Ashley Bragg (b) (4)	13 Oct 2020 20:02:30

US3332059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered '13:45'	Ashley Bragg (b) (4)	13 Oct 2020 20:02:30

US3332059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered '13 Oct 2020 13:45'	System	13 Oct 2020 20:02:30

US3332059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:29:55
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Oct 2020 20:02:33

US3332059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	13 Oct 2020 20:02:33

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 64'	System	24 Aug 2020 21:25:51

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-10-24T07:48:14', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '590a8b44-343d-40f4-aa64-09fd319ba098'	System	24 Oct 2020 13:48:32
User entered 'No (N)'	System	24 Oct 2020 13:48:32

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-10-24T07:48:23', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '590a8b44-343d-40f4-aa64-09fd319ba098'	System	24 Oct 2020 13:48:32
User entered 'No (N)'	System	24 Oct 2020 13:48:32

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-10-24T07:48:27', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '590a8b44-343d-40f4-aa64-09fd319ba098' User entered '24 Oct 2020 07:48:27'	System	24 Oct 2020 13:48:32
	System	24 Oct 2020 13:48:32

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 21:25:51

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 71'	System	24 Aug 2020 21:25:51

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-10-31T09:45:24', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e9783bf7-6003-446e-b3b3-9a1e8655602d' User entered 'No (N)'	System	31 Oct 2020 15:45:35
	System	31 Oct 2020 15:45:35

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-10-31T09:45:27', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e9783bf7-6003-446e-b3b3-9a1e8655602d' User entered 'No (N)'	System	31 Oct 2020 15:45:35
	System	31 Oct 2020 15:45:35

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-10-31T09:45:30', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e9783bf7-6003-446e-b3b3-9a1e8655602d' User entered '31 Oct 2020 09:45:30'	System	31 Oct 2020 15:45:35
	System	31 Oct 2020 15:45:35

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 21:25:51

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered 'Day 78'	System	24 Aug 2020 21:25:51

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-11-07T08:04:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '153bfbfb-c776-45a3-8c1a-f2ead7dfb3d3' User entered 'No (N)'	System	07 Nov 2020 15:05:05
	System	07 Nov 2020 15:05:05

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-11-07T08:04:58', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '153bfbfb-c776-45a3-8c1a-f2ead7dfb3d3' User entered 'No (N)'	System	07 Nov 2020 15:05:05
	System	07 Nov 2020 15:05:05

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-11-07T08:05:02', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '153bfbfb-c776-45a3-8c1a-f2ead7dfb3d3' User entered '07 Nov 2020 08:05:02'	System	07 Nov 2020 15:05:05
	System	07 Nov 2020 15:05:05

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 21:25:51

US3332059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:57:12
Data entry locked.	System	24 Aug 2020 21:25:51
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 21:25:51

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-11-28T16:50:46', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dc75c1a4-df2b-4d52-9517-e40369e9b48e'	System	28 Nov 2020 23:51:00
User entered 'No (N)'	System	28 Nov 2020 23:51:00

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-11-28T16:50:53', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dc75c1a4-df2b-4d52-9517-e40369e9b48e'	System	28 Nov 2020 23:51:00
User entered 'No (N)'	System	28 Nov 2020 23:51:00

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-11-28T16:50:57', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dc75c1a4-df2b-4d52-9517-e40369e9b48e' User entered '28 Nov 2020 16:50:57'	System	28 Nov 2020 23:51:00
	System	28 Nov 2020 23:51:00

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-12T17:59:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '88dde8d-945d-4775-998a-91f6fa5b9163'	System	13 Dec 2020 01:00:22
User entered 'No (N)'	System	13 Dec 2020 01:00:22

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-12T17:59:38', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '88dde8d-945d-4775-998a-91f6fa5b9163'	System	13 Dec 2020 01:00:22
User entered 'Yes (Y)'	System	13 Dec 2020 01:00:22

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-12T18:00:06', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '88dde8d-945d-4775-998a-91f6fa5b9163'	System	13 Dec 2020 01:00:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 01:00:22

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-12T18:00:12', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '88dde8d-945d-4775-998a-91f6fa5b9163' User entered '12 Dec 2020 18:00:12'	System	13 Dec 2020 01:00:22
	System	13 Dec 2020 01:00:22

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-16T07:19:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '197f60e9-c85d-47cd-a8f7-eade4817ef25'	System	16 Dec 2020 14:20:06
User entered 'No (N)'	System	16 Dec 2020 14:20:06

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-16T07:20:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '197f60e9-c85d-47cd-a8f7-eade4817ef25'	System	16 Dec 2020 14:20:06
User entered 'No (N)'	System	16 Dec 2020 14:20:06

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-16T07:20:03', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '197f60e9-c85d-47cd-a8f7-eade4817ef25' User entered '16 Dec 2020 07:20:03'	System	16 Dec 2020 14:20:06
	System	16 Dec 2020 14:20:06

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-23T16:29:03', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '069d1548-56c6-46d8-9a42-0fa12d51e5cd' User entered 'No (N)'	System	23 Dec 2020 23:29:14
	System	23 Dec 2020 23:29:14

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-23T16:29:07', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '069d1548-56c6-46d8-9a42-0fa12d51e5cd' User entered 'No (N)'	System	23 Dec 2020 23:29:14
	System	23 Dec 2020 23:29:14

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-23T16:29:09', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '069d1548-56c6-46d8-9a42-0fa12d51e5cd' User entered '23 Dec 2020 16:29:09'	System	23 Dec 2020 23:29:14
	System	23 Dec 2020 23:29:14

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-30T08:10:34', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'da7b2a29-b3bd-4091-b3f6-dac0683c0483' User entered 'No (N)'	System	30 Dec 2020 15:10:45
	System	30 Dec 2020 15:10:45

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-30T08:10:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'da7b2a29-b3bd-4091-b3f6-dac0683c0483' User entered 'No (N)'	System	30 Dec 2020 15:10:45
	System	30 Dec 2020 15:10:45

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2020-12-30T08:10:43', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'da7b2a29-b3bd-4091-b3f6-dac0683c0483' User entered '30 Dec 2020 08:10:43'	System	30 Dec 2020 15:10:45
	System	30 Dec 2020 15:10:45

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-07T16:53:46', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'fc244ff9-8bd4-4a62-b7fe-cdbc339c021c' User entered 'No (N)'	System	07 Jan 2021 23:53:57

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-07T16:53:51', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'fc244ff9-8bd4-4a62-b7fe-cdbc339c021c' User entered 'No (N)'	System	07 Jan 2021 23:53:57

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-07T16:53:54', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'fc244ff9-8bd4-4a62-b7fe-cdbc339c021c' User entered '07 Jan 2021 16:53:54'	System	07 Jan 2021 23:53:57

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-13T17:06:17', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3523b22e-7371-4f9f-b722-8bf8284d72fe'	System	14 Jan 2021 00:06:28
User entered 'No (N)'	System	14 Jan 2021 00:06:28

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-13T17:06:21', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3523b22e-7371-4f9f-b722-8bf8284d72fe'	System	14 Jan 2021 00:06:28
User entered 'No (N)'	System	14 Jan 2021 00:06:28

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-13T17:06:23', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '3523b22e-7371-4f9f-b722-8bf8284d72fe'	System	14 Jan 2021 00:06:28
User entered '13 Jan 2021 17:06:23'	System	14 Jan 2021 00:06:28

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-22T12:00:35', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '086ea2f2-1ed5-4763-b8be-fffb4f63a49d' User entered 'No (N)'	System	22 Jan 2021 19:00:47

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-22T12:00:40', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '086ea2f2-1ed5-4763-b8be-fffb4f63a49d' User entered 'No (N)'	System	22 Jan 2021 19:00:47

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-22T12:00:42', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '086ea2f2-1ed5-4763-b8be-fffb4f63a49d' User entered '22 Jan 2021 12:00:42'	System	22 Jan 2021 19:00:47
	System	22 Jan 2021 19:00:47

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-31T17:58:13', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e1b48b1d-ab01-46bc-ada6-5035f61a13e8' User entered 'No (N)'	System	01 Feb 2021 00:58:23
	System	01 Feb 2021 00:58:23

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-31T17:58:17', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e1b48b1d-ab01-46bc-ada6-5035f61a13e8' User entered 'No (N)'	System	01 Feb 2021 00:58:23

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-01-31T17:58:19', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'e1b48b1d-ab01-46bc-ada6-5035f61a13e8' User entered '31 Jan 2021 17:58:19'	System	01 Feb 2021 00:58:23
	System	01 Feb 2021 00:58:23

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-03T08:43:35', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '6f2a9622-c6ac-44dc-913f-aff37f379d2d' User entered 'No (N)'	System	03 Feb 2021 15:43:47

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-03T08:43:38', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '6f2a9622-c6ac-44dc-913f-aff37f379d2d' User entered 'No (N)'	System	03 Feb 2021 15:43:47

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-03T08:43:42', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '6f2a9622-c6ac-44dc-913f-aff37f379d2d' User entered '03 Feb 2021 08:43:42'	System	03 Feb 2021 15:43:47
	System	03 Feb 2021 15:43:47

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-10T08:15:09', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '7a914c3c-3ae9-4b61-ba99-8d741d7f0b89' User entered 'No (N)'	System	10 Feb 2021 15:15:21
	System	10 Feb 2021 15:15:21

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-10T08:15:15', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '7a914c3c-3ae9-4b61-ba99-8d741d7f0b89' User entered 'No (N)'	System	10 Feb 2021 15:15:21
	System	10 Feb 2021 15:15:21

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-10T08:15:18', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '7a914c3c-3ae9-4b61-ba99-8d741d7f0b89' User entered '10 Feb 2021 08:15:18'	System	10 Feb 2021 15:15:21
	System	10 Feb 2021 15:15:21

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-17T08:36:18', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '92666949-6ca4-4acb-9478-225005ed4491'	System	17 Feb 2021 15:36:42
User entered 'Yes (Y)'	System	17 Feb 2021 15:36:42

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-17T08:36:22', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '92666949-6ca4-4acb-9478-225005ed4491'	System	17 Feb 2021 15:36:42
User entered 'No (N)'	System	17 Feb 2021 15:36:42

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-17T08:36:29', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '92666949-6ca4-4acb-9478-225005ed4491'	System	17 Feb 2021 15:36:42
User entered 'No (N)'	System	17 Feb 2021 15:36:42

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-17T08:36:33', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '92666949-6ca4-4acb-9478-225005ed4491'	System	17 Feb 2021 15:36:42
User entered 'No (N)'	System	17 Feb 2021 15:36:42

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-17T08:36:39', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '92666949-6ca4-4acb-9478-225005ed4491'	System	17 Feb 2021 15:36:42
User entered '17 Feb 2021 08:36:39'	System	17 Feb 2021 15:36:42

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-27T18:08:34-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '59ad81b0-5058-4c10-a42c-f37d05b0b35e' User entered 'No (N)'	System	28 Feb 2021 01:10:26
	System	28 Feb 2021 01:10:26

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-27T18:08:38-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '59ad81b0-5058-4c10-a42c-f37d05b0b35e' User entered 'No (N)'	System	28 Feb 2021 01:10:26
	System	28 Feb 2021 01:10:26

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-27T18:08:41-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '59ad81b0-5058-4c10-a42c-f37d05b0b35e' User entered '28 Feb 2021 01:08:41'	System	28 Feb 2021 01:10:26
	System	28 Feb 2021 01:10:26

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-03T07:59:13-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1aa51ebd-31ac-4239-9597-723655a063c5'	System	03 Mar 2021 14:59:48
User entered 'Yes (Y)'	System	03 Mar 2021 14:59:48

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-03T07:59:17-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1aa51ebd-31ac-4239-9597-723655a063c5'	System	03 Mar 2021 14:59:48
User entered 'No (N)'	System	03 Mar 2021 14:59:48

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-03T07:59:23-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1aa51ebd-31ac-4239-9597-723655a063c5'	System	03 Mar 2021 14:59:48
User entered 'No (N)'	System	03 Mar 2021 14:59:48

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-03T07:59:28-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1aa51ebd-31ac-4239-9597-723655a063c5'	System	03 Mar 2021 14:59:48
User entered 'Yes (Y)'	System	03 Mar 2021 14:59:48

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-03T07:59:32-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1aa51ebd-31ac-4239-9597-723655a063c5'	System	03 Mar 2021 14:59:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Mar 2021 14:59:48

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-03T07:59:36-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '1aa51ebd-31ac-4239-9597-723655a063c5'	System	03 Mar 2021 14:59:48
User entered '03 Mar 2021 07:59:36'	System	03 Mar 2021 14:59:48

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-10T07:05:29-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dfb5ff43-c453-4e28-93e0-3cc511863570'	System	10 Mar 2021 14:06:20
User entered 'Yes (Y)'	System	10 Mar 2021 14:06:20

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-10T07:05:35-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dfb5ff43-c453-4e28-93e0-3cc511863570'	System	10 Mar 2021 14:06:20
User entered 'No (N)'	System	10 Mar 2021 14:06:20

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-10T07:05:48-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dfb5ff43-c453-4e28-93e0-3cc511863570'	System	10 Mar 2021 14:06:20
User entered 'No (N)'	System	10 Mar 2021 14:06:20

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-10T07:05:53-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dfb5ff43-c453-4e28-93e0-3cc511863570'	System	10 Mar 2021 14:06:20
User entered 'Yes (Y)'	System	10 Mar 2021 14:06:20

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-10T07:06:02-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dfb5ff43-c453-4e28-93e0-3cc511863570'	System	10 Mar 2021 14:06:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Mar 2021 14:06:20

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-10T07:06:08-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'dfb5ff43-c453-4e28-93e0-3cc511863570'	System	10 Mar 2021 14:06:20
User entered '10 Mar 2021 07:06:08'	System	10 Mar 2021 14:06:20

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-17T08:34:24-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '86ac6c98-e7b7-474b-9c76-648f929ea7ea' User entered 'No (N)'	System	17 Mar 2021 14:34:33
	System	17 Mar 2021 14:34:33

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-17T08:34:27-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '86ac6c98-e7b7-474b-9c76-648f929ea7ea' User entered 'No (N)'	System	17 Mar 2021 14:34:33
	System	17 Mar 2021 14:34:33

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-17T08:34:30-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '86ac6c98-e7b7-474b-9c76-648f929ea7ea' User entered '17 Mar 2021 08:34:30'	System	17 Mar 2021 14:34:33
	System	17 Mar 2021 14:34:33

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-24T07:46:17-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '18874fb3-2740-4f1a-9dc2-c31ad4d0e12c'	System	24 Mar 2021 13:46:25
User entered 'No (N)'	System	24 Mar 2021 13:46:25

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-24T07:46:20-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '18874fb3-2740-4f1a-9dc2-c31ad4d0e12c'	System	24 Mar 2021 13:46:25
User entered 'No (N)'	System	24 Mar 2021 13:46:25

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-24T07:46:23-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '18874fb3-2740-4f1a-9dc2-c31ad4d0e12c'	System	24 Mar 2021 13:46:25
User entered '24 Mar 2021 07:46:23'	System	24 Mar 2021 13:46:25

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-31T07:12:30-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f2bce4fe-16c1-4dac-9fb9-4d836d28cefb' User entered 'No (N)'	System	31 Mar 2021 14:12:42
	System	31 Mar 2021 14:12:42

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-31T07:12:34-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f2bce4fe-16c1-4dac-9fb9-4d836d28cefb' User entered 'No (N)'	System	31 Mar 2021 14:12:42
	System	31 Mar 2021 14:12:42

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-03-31T07:12:37-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'f2bce4fe-16c1-4dac-9fb9-4d836d28cefb' User entered '31 Mar 2021 07:12:37'	System	31 Mar 2021 14:12:42
	System	31 Mar 2021 14:12:42

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-09T12:09:24-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'bc077ffc-f6fb-4939-b206-2512cf5953b1'	System	09 Apr 2021 18:09:36
User entered 'No (N)'	System	09 Apr 2021 18:09:36

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-09T12:09:29-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'bc077ffc-f6fb-4939-b206-2512cf5953b1'	System	09 Apr 2021 18:09:36
User entered 'No (N)'	System	09 Apr 2021 18:09:36

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-09T12:09:32-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'bc077ffc-f6fb-4939-b206-2512cf5953b1' User entered '09 Apr 2021 12:09:32'	System	09 Apr 2021 18:09:36
	System	09 Apr 2021 18:09:36

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-16T12:00:15-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2f6d9038-a5c3-4a9b-a190-d0d612b8d4e9' User entered 'No (N)'	System	16 Apr 2021 18:00:26
	System	16 Apr 2021 18:00:26

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-16T12:00:17-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2f6d9038-a5c3-4a9b-a190-d0d612b8d4e9' User entered 'No (N)'	System	16 Apr 2021 18:00:26
	System	16 Apr 2021 18:00:26

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-16T12:00:20-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '2f6d9038-a5c3-4a9b-a190-d0d612b8d4e9' User entered '16 Apr 2021 12:00:20'	System	16 Apr 2021 18:00:26
	System	16 Apr 2021 18:00:26

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-21T07:50:41-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'fdeced58-63be-4f59-ac6a-4e434a2ec023'	System	21 Apr 2021 13:50:56
User entered 'No (N)'	System	21 Apr 2021 13:50:56

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

Have you been exposed to someone with 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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-21T07:50:47-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'fdeced58-63be-4f59-ac6a-4e434a2ec023'	System	21 Apr 2021 13:50:56
User entered 'No (N)'	System	21 Apr 2021 13:50:56

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-21T07:50:52-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'fdeced58-63be-4f59-ac6a-4e434a2ec023'	System	21 Apr 2021 13:50:56
User entered '21 Apr 2021 07:50:52'	System	21 Apr 2021 13:50:56

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[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 (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-30T12:00:45-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ee919d2b-b8db-4cde-9d28-c3b8e99138e0'	System	30 Apr 2021 18:01:30
User entered 'Yes (Y)'	System	30 Apr 2021 18:01:30

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Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-30T12:00:53-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ee919d2b-b8db-4cde-9d28-c3b8e99138e0'	System	30 Apr 2021 18:01:30
User entered 'No (N)'	System	30 Apr 2021 18:01:30

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-30T12:00:58-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ee919d2b-b8db-4cde-9d28-c3b8e99138e0' User entered 'No (N)'	System	30 Apr 2021 18:01:30

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-30T12:01:01-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ee919d2b-b8db-4cde-9d28-c3b8e99138e0' User entered 'Yes (Y)'	System	30 Apr 2021 18:01:30
	System	30 Apr 2021 18:01:30

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-30T12:01:05-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ee919d2b-b8db-4cde-9d28-c3b8e99138e0'	System	30 Apr 2021 18:01:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Apr 2021 18:01:30

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-04-30T12:01:07-06:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: 'ee919d2b-b8db-4cde-9d28-c3b8e99138e0' User entered '30 Apr 2021 12:01:07'	System	30 Apr 2021 18:01:30
	System	30 Apr 2021 18:01:30

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:03:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 02:03:35

US3332059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:03:35
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 02:03:35

US3332059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:17:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-27T18:08:47-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '8962047f-e911-4832-add3-deb9f63b8a25'	System	28 Feb 2021 01:10:30
User entered 'No (N)'	System	28 Feb 2021 01:10:30

US3332059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:08

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:17:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCD170E8-DA34-4EC0-ADA8-F48C4A4BF682)', Time: '2021-02-27T18:08:55-07:00', User OID: 'PatientReportedOutcome (US3332059)', ODM File OID: '8962047f-e911-4832-add3-deb9f63b8a25'	System	28 Feb 2021 01:10:30
User entered '28 Feb 2021 01:08:55'	System	28 Feb 2021 01:10:30

US3332059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:38

US3332059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:38

US3332059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:38

US3332059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:38

US3332059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:44

US3332059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:58:09
User entered 'I'	System	14 Dec 2020 21:02:44

US3332059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:53

US3332059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:53

US3332059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:53

US3332059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:53

US3332059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:02:58

US3332059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered 'I'	System	14 Dec 2020 21:02:58

US3332059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	14 Jan 2021 00:07:07

US3332059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '13 Jan 2021'	Ashley Bragg (b) (4)	14 Jan 2021 00:07:07

US3332059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 00:07:07

US3332059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 00:07:07

US3332059

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	14 Jan 2021 00:06:58

US3332059

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered '1'	System	14 Jan 2021 00:06:58

US3332059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	12 Feb 2021 22:52:55

US3332059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '12 Feb 2021'	(b) (4) Colby Bostock (b) (4)	12 Feb 2021 22:52:55

US3332059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colby Bostock (b) (4)	12 Feb 2021 22:52:55

US3332059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	(b) (4) Colby Bostock (b) (4)	12 Feb 2021 22:52:55

US3332059

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	12 Feb 2021 22:54:28

US3332059

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered '1'	System	12 Feb 2021 22:54:28

US3332059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:34

US3332059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '3 Mar 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:34

US3332059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Clinic (Clinic)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:34

US3332059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered 'VISIT4'	System	03 Mar 2021 18:47:34

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered empty.	System	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered empty.	System	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered empty.	System	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered empty.	System	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered empty.	System	30 Mar 2021 17:33:08

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21

US3332059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21

US3332059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:40

US3332059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '3 Mar 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:40

US3332059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:53

US3332059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '3 Mar 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:53

US3332059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '08:35'	Ashley Bragg (b) (4)	03 Mar 2021 18:47:53

US3332059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered '3 Mar 2021 08:35'	System	03 Mar 2021 18:47:53

US3332059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:57

US3332059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:21
User entered 'I'	System	03 Mar 2021 18:47:57

US3332059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:25
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	13 Apr 2021 20:40:47
	(b) (4)	

US3332059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:25
	(b) (4)	
User entered '13 Apr 2021'	Ashley Bragg (b) (4)	13 Apr 2021 20:40:47
	(b) (4)	

US3332059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	13 Apr 2021 20:40:47

US3332059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:25
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	13 Apr 2021 20:40:47
	(b) (4)	

US3332059

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:25
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	13 Apr 2021 20:40:51
	(b) (4)	

US3332059

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 20:40:51

US3332059

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	03 Mar 2021 18:46:19

US3332059

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '3 Mar 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:46:19

US3332059

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[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 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Clinic (Clinic)'	Ashley Bragg (b) (4)	03 Mar 2021 18:46:19

US3332059

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User entered 'UNBLND_DECIDE'	System	03 Mar 2021 18:46:19

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '3 Mar 2021'	Ashley Bragg (b) (4)	03 Mar 2021 18:46:37

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:05:16
User entered '0'	(b) (4) Ashley Bragg (b) (4)	08 Apr 2021 22:37:58
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:34:09

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:46:37

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:05:16
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:10:30
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Ashley Bragg (b) (4) (b) (4)	08 Apr 2021 22:38:13
User entered 'Amendment 6 or later (Amendment 6 or later)'	Ashley Bragg (b) (4) (b) (4)	08 Apr 2021 22:37:58
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:52:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:34:09

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '3 Mar 2021'	Ashley Bragg (b) (4)	03 Mar 2021 18:46:37

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'mRNA-1273 (mRNA-1273)'	Ashley Bragg (b) (4)	03 Mar 2021 18:46:37

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'mRNA-1273 (mRNA-1273)'	Ashley Bragg (b) (4)	03 Mar 2021 18:46:37

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'mRNA-1273 (mRNA-1273)'	Ashley Bragg (b) (4)	03 Mar 2021 18:46:37

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:46:37

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User entered empty.	System	03 Mar 2021 18:46:37

US3332059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User entered empty.	System	03 Mar 2021 18:46:37

US3332059

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:46:58

US3332059

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '3 Mar 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:46:58

US3332059

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '08:35'	Ashley Bragg (b) (4)	03 Mar 2021 18:46:58

US3332059

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User entered '3 Mar 2021 08:35'	System	03 Mar 2021 18:46:58

US3332059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:12

US3332059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 11:15:58
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' answered with 'correction sent to lab' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:37:00
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:16:03
User entered '3 Mar 2021'	Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:12

US3332059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
User entered '08:33'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 18:47:12

US3332059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:08

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:07
User entered '3 Mar 2021 08:33'	System	03 Mar 2021 18:47:12

US3332059

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:05:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	Ty Henry (b) (4)	28 Sep 2020 20:25:38

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SYMPTOM DEEMED RELATED TO INVESTIGATIONAL PRODUCT AND NOT COVID-19 PER PI' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:39:39
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	Lindsey Bevan (b) (4)	04 Nov 2020 21:36:28
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:59:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 20:34:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 20:34:47
Data point term sent to Coder System	System	02 Oct 2020 20:33:32
User entered 'fatigue'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'No (N)'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User closed query 'Per DM CLR: This AE started after Day 7 from dosing, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 04:24:30
Query 'Per DM CLR: This AE started after Day 7 from dosing, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' answered with 'AE started the same day dose 2 was administered and continued until resolution on day 12. This is a solicited event.' (Site from DM).	Ashley Bragg (b) (4) (b) (4)	26 Feb 2021 22:34:47
User entered 'Yes (Y)' reason for change: Per Query Resolution	Ashley Bragg (b) (4) (b) (4)	26 Feb 2021 22:33:54
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	26 Feb 2021 22:29:52
User opened query 'Per DM CLR: This AE started after Day 7 from dosing, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 16:58:29
User entered 'Yes (Y)'	Colby Bostock (b) (4) (b) (4)	02 Oct 2020 20:32:50

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'No (N)'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 18 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:16:15
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 18 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'DATA UPDATED' (Site from DM).	Lindsey Bevan (b) (4)	04 Nov 2020 21:48:02
User entered '18 Sep 2020' reason for change: Data Entry Error	Lindsey Bevan (b) (4)	04 Nov 2020 21:47:39
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 18 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:38:03
User entered '19 Sep 2020'	Colby Bostock (b) (4) (b) (4)	02 Oct 2020 20:32:50

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '10:00'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:00'	System	04 Nov 2020 21:47:39
User entered '19 Sep 2020 10:00'	System	02 Oct 2020 20:32:50

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'No (N)'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '29 Sep 2020'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:35:07
User entered '09:00' reason for change: Data Entry Error	Colby Bostock (b) (4)	02 Oct 2020 20:35:07
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:32:50
User entered empty.	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 09:00'	System	02 Oct 2020 20:35:07
User entered empty.	System	02 Oct 2020 20:32:50

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'No (N)'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'Related (RELATED)'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User closed query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use If adverse event started BEFORE first dose. If adverse event started and ended during a time period when study dose was interrupted (not given/held) and If adverse event started AFTER last dose. Please consider to update this field appropriately or else, clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:05:24
Query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use If adverse event started BEFORE first dose. If adverse event started and ended during a time period when study dose was interrupted (not given/held) and If adverse event started AFTER last dose. Please consider to update this field appropriately or else, clarify. Thank you' answered with 'DATA UPDATED' (Site from DM).	Lindsey Bevan (b) (4)	04 Nov 2020 21:47:59
User entered 'None (NONE)' reason for change: Data Entry Error	Lindsey Bevan (b) (4)	04 Nov 2020 21:47:39
User opened query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use If adverse event started BEFORE first dose. If adverse event started and ended during a time period when study dose was interrupted (not given/held) and If adverse event started AFTER last dose. Please consider to update this field appropriately or else, clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:46:01
User entered 'Not Applicable (NOT APPLICABLE)'	Colby Bostock (b) (4) (b) (4)	02 Oct 2020 20:32:50

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'I'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered '0'	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Colby Bostock (b) (4) (b) (4)	02 Oct 2020 20:32:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered empty.	Colby Bostock (b) (4)	02 Oct 2020 20:32:50
	(b) (4)	

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 20:32:50

US3332059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 20:32:50

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Epistaxis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 17:43:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 17:43:41
User signature succeeded.	James Peterson (b) (4) (b) (4)	12 Mar 2021 17:28:10
Data point term sent to Coder	System	03 Mar 2021 21:20:07
User entered 'Nose bleeds-intermittent epistaxis'	Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '17 Feb 2021'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered empty.	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User entered empty.	System	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:25
Signature has been broken.	(b) (4)	
	Ashley Bragg (b) (4)	13 Apr 2021 20:36:18
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Ashley Bragg (b) (4)	13 Apr 2021 20:36:18
User signature succeeded.	(b) (4)	
	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'Yes (Y)'	(b) (4)	
	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:25
Signature has been broken.	(b) (4)	
	Ashley Bragg (b) (4)	13 Apr 2021 20:36:18
	(b) (4)	
User entered '12 Mar 2021' reason for change: New Information	Ashley Bragg (b) (4)	13 Apr 2021 20:36:18
User signature succeeded.	(b) (4)	
	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User entered empty.	System	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'No (N)'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '0'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '0'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '0'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered empty.	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered empty.	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

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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)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered empty.	(b) (4) Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '0'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '0'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '0'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '0'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered '0'	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

US3332059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered 'I'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:25
Signature has been broken.	(b) (4)	
	Ashley Bragg (b) (4)	13 Apr 2021 20:36:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Ashley Bragg (b) (4)	13 Apr 2021 20:36:18
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Ashley Bragg (b) (4)	03 Mar 2021 21:19:27
	(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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:10
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	03 Mar 2021 21:19:27

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User entered '0'	System	03 Mar 2021 21:19:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59
User entered 'I'	System	03 Mar 2021 21:19:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:38:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 14:46:20
User entered		
'USA-US202-2021-mRNA-1273-P301000006'	System	30 Apr 2021 14:46:15
User entered 'New'	(b) (4), (b) (6)	30 Apr 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Pelvic fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Apr 2021 07:57:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 07:57:22
Data point term sent to Coder	System	29 Apr 2021 22:00:57
User entered 'Multiple pelvic fractures'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:59:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:05:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:59:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:59:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
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).	(b) (4) System	29 Apr 2021 22:07:44
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	29 Apr 2021 22:06:15
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	29 Apr 2021 22:06:15
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	29 Apr 2021 22:06:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 22:06:15
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	29 Apr 2021 21:59:57
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:59:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 01:59:37
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'correct as entered' (Site from System).	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 22:08:46
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Apr 2021 22:07:44
User entered '1' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 22:07:44
User entered '0'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:59:57

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021' reason for change: Data Entry Error	Ashley Bragg (b) (4)	29 Apr 2021 22:07:44
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:21:47
User entered empty.	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:59:57

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Ashley Bragg (b) (4)	29 Apr 2021 22:07:44
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'I'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'I'	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:59:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:59:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 22:06:15
User entered '0'	System	29 Apr 2021 21:59:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 21:59:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 22:21:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:46:55
User entered 'USA-US202-2021-mRNA-1273-P301000006'	(b) (4), (b) (6)	30 Apr 2021 14:46:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fractured ribs - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 08:16:24
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 08:16:24
	(b) (4)	
Data point term sent to Coder	System	29 Apr 2021 22:25:15
User entered 'RIGHT RIBS #4-8 FRACTURES'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 02:00:06
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'ADDED' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 22:26:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Apr 2021 22:25:03
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered '22 Apr 2021' reason for change: Data Entry Error	(b) (4)	29 Apr 2021 22:25:55
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 22:25:03

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:47:22
User entered 'USA-US202-2021-mRNA-1273-P301000006'	(b) (4), (b) (6)	30 Apr 2021 14:47:18

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Fractured sacrum, LLT: Fractured sacrum - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 08:05:23
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 08:05:23
	(b) (4)	
Data point term sent to Coder	System	29 Apr 2021 22:29:17
User entered 'CLOSED SACRAL FRACTURE'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
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).	(b) (4) System	29 Apr 2021 22:28:49
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	29 Apr 2021 22:28:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 01:58:59
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'ENTERED' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 22:29:06
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		29 Apr 2021 22:28:49
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).	System	29 Apr 2021 22:28:49
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Apr 2021 22:28:49
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:28:49
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	29 Apr 2021 22:28:27
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 22:28:27

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:06
User entered 'USA-US202-2021-mRNA-1273-P301000006'	(b) (4), (b) (6)	30 Apr 2021 14:48:00

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Acetabulum fracture, LLT: Acetabulum fracture - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:32:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:32:05
	(b) (4)	
Data point term sent to Coder	System	29 Apr 2021 22:31:18
User entered 'RIGHT ACETABULAR FRACTURE'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 02:00:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'ENTERED' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 22:31:38
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Apr 2021 22:30:24
User entered '1'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 22:30:24

US3332059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 22:30:24

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User closed query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 06:57:27
Query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'Medication updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	05 Oct 2020 18:03:17
User opened query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:22:24
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Sep 2020 16:40:48

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Jan 2021 17:47:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Jan 2021 17:47:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:45:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:45:40
Data point term sent to Coder	System	09 Sep 2020 16:44:06
User entered 'Escitalopram Oxalate'	Ty Henry (b) (4) (b) (4)	09 Sep 2020 16:43:38

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Anxiety'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '15'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'mg (mg)'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'once daily (QD)'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'un May 2010'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:43:38
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:43:38

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:43:38

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 16:43:38

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN SUCCINATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 16:46:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 16:46:46
Data point term sent to Coder	System	09 Sep 2020 16:45:11
User entered 'Sumatriptan Succinate'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Migraines'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '100'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'mg (mg)'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'as needed (PRN)'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '21 Oct 2010'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:44:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:44:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:44:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:44:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 16:57:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:57:56
Data point term sent to Coder User entered 'Prolia'	System Ty Henry (b) (4) (b) (4)	09 Sep 2020 16:56:49 09 Sep 2020 16:56:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Osteoporosis'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '60' reason for change: Data Entry Error	Megan Grimmatt (b) (4)	16 Dec 2020 16:31:26
	(b) (4)	
User entered '1'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Megan Grimmatt (b) (4)	16 Dec 2020 16:31:26
	(b) (4)	
User entered 'Other (OTHER)'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 04:27:51
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'answered' (Site from DM).	Megan Grimmatt (b) (4) (b) (4)	16 Dec 2020 16:31:34
User entered empty; reason for change Data Entry Error	Megan Grimmatt (b) (4) (b) (4)	16 Dec 2020 16:31:26
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 11:48:45
User entered 'Infusion'	Ty Henry (b) (4) (b) (4)	09 Sep 2020 16:56:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'other (OTHER)'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Every 6 months'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Ty Henry (b) (4) (b) (4)	09 Sep 2020 16:56:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'un UNK 2017'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:56:47
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:56:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:56:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:56:47

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 16:58:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:58:40
Data point term sent to Coder	System	09 Sep 2020 16:57:49
User entered 'Calcium'	Ty Henry (b) (4) (b) (4)	09 Sep 2020 16:57:40

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Supplement'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '1500'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'mg (mg)'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'once daily (QD)'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'un UNK 2013'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:57:40
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:57:40

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:57:40

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 16:57:40

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:56:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:56:49

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:27:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:27:53

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 16:59:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 16:59:47
Data point term sent to Coder	System	09 Sep 2020 16:58:51
User entered 'Centrum Silver'	Ty Henry (b) (4)	09 Sep 2020 16:58:42

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Supplement'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '1'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'tablet (TABLET)'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'once daily (QD)'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'un UNK 2013'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:58:42
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:58:42

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:58:42

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 16:58:42

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: KRILL OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 16:33:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 16:33:03
User signature succeeded.	James Peterson (b) (4) (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: KRILL OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:00:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:00:54
Data point term sent to Coder	System	09 Sep 2020 16:59:52
User entered 'Krill Oil'	Ty Henry (b) (4) (b) (4)	09 Sep 2020 16:59:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Supplement'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '500'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'mg (mg)'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'once daily (QD)'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'un UNK 2015'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 16:59:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:59:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:59:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 16:59:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 17:04:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 17:04:54
Data point term sent to Coder	System	09 Sep 2020 17:03:59
User entered 'Vitamin D3'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Supplement'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '50'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'ug (ug)'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'once daily (QD)'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'un UNK 2013'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 17:03:50
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:03:50

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:03:50

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 17:03:50

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Sep 2020 12:30:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:30:44
Data point term sent to Coder	System	09 Sep 2020 17:06:03
User entered 'Naproxen Sodium'	Ty Henry (b) (4) (b) (4)	09 Sep 2020 17:06:00

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Low Back Pinched Nerve'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '440'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'mg (mg)'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'as needed (PRN)'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'un UNK 1980'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	09 Sep 2020 17:06:00
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:06:00

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:06:00

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:06:00

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 00:25:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 00:25:47
Data point term sent to Coder	System	16 Sep 2020 17:27:36
User entered 'Aleve'	Ty Henry (b) (4) (b) (4)	16 Sep 2020 17:27:04

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Exercise Related Muscle Soreness'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 04:28:48
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'completed' (Site from DM).	Megan Grimmatt (b) (4) (b) (4)	16 Dec 2020 16:36:13
User entered '440' reason for change: Data Entry Error	Megan Grimmatt (b) (4) (b) (4)	16 Dec 2020 16:36:06
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 11:49:19
User entered '2'	Ty Henry (b) (4) (b) (4)	16 Sep 2020 17:27:04

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Megan Grimmatt (b) (4)	16 Dec 2020 16:36:06
	(b) (4)	
User entered 'tablet (TABLET)'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'as needed (PRN)'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'un UNK 1980'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	16 Sep 2020 17:27:04
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 17:27:04

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 17:27:04

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 17:27:04

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 12:24:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 12:24:18
Data point term sent to Coder User entered 'Aleve'	System Ty Henry (b) (4)	05 Oct 2020 18:03:09 05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'No (N)'	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MUSCLE ACHES, JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MUSCLE ACHES, JOINT PAIN did not meet the AE reporting criteria.'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:30:02
(Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MUSCLE ACHES, JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MUSCLE ACHES, JOINT PAIN did not meet the AE reporting criteria.'	Sean Hansen (b) (4) (b) (4)	26 Jan 2021 22:22:11
' answered with 'These solicited reactions did not meet AE reporting criteria.' (Site from DM).		

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MUSCLE ACHES, JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MUSCLE ACHES, JOINT PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:02:51
User entered 'Headache, Muscle aches, Joint pain'	Ty Henry (b) (4) (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '440' reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	16 Dec 2020 16:36:35
User entered '2'	(b) (4)	
	Ty Henry (b) (4)	05 Oct 2020 18:02:20
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	16 Dec 2020 16:36:35
	(b) (4)	
User entered 'tablet (TABLET)'	Ty Henry (b) (4)	05 Oct 2020 18:02:20
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'as needed (PRN)'	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '19 Sep 2020'	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '0'	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'No (N)'	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '19 Sep 2020'	Ty Henry (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User closed query 'Per CDM CLR re-query: Thank you for your answer. However, no Ae matches with this concomitant medication. Please consider adding missing AE or confirm that this solicited adverse reaction of headache, muscle aches, joint pain did not meet the AE reporting criteria. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 13:59:31
Query 'Per CDM CLR re-query: Thank you for your answer. However, no Ae matches with this concomitant medication. Please consider adding missing AE or confirm that this solicited adverse reaction of headache, muscle aches, joint pain did not meet the AE reporting criteria. Thank you!' answered with 'confirming that these are solicited AEs and will not be duplicated in reporting ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:46:05
User opened query 'Per CDM CLR re-query: Thank you for your answer. However, no Ae matches with this concomitant medication. Please consider adding missing AE or confirm that this solicited adverse reaction of headache, muscle aches, joint pain did not meet the AE reporting criteria. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:45:11
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MUSCLE ACHES, JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MUSCLE ACHES, JOINT PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:43:53

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MUSCLE ACHES, JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MUSCLE ACHES, JOINT PAIN did not meet the AE reporting criteria.' answered with 'we do not report solicited AEs ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:06:06
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MUSCLE ACHES, JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MUSCLE ACHES, JOINT PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 18:33:20
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User entered empty.	System	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User entered empty.	System	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:24
User entered empty.	System	05 Oct 2020 18:02:20

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 15:57:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 15:57:02
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)	13 Oct 2020 15:56:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 15:56:20
Data point term sent to Coder User entered 'Influenza Vaccine'	System Ty Henry (b) (4)	13 Oct 2020 15:55:29 13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Yes (Y)'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Influenza Prophylaxis'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'I'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Other (OTHER)'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Injection'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'once (ONCE)'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	(b) (4)	13 Oct 2020 15:54:55
	Ty Henry (b) (4)	
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered empty.	(b) (4)	13 Oct 2020 15:54:55
	Ty Henry (b) (4)	
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '09 Oct 2020'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '0'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'No (N)'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered '09 Oct 2020'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
User entered 'No (N)'	Ty Henry (b) (4)	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User entered empty.	System	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User entered empty.	System	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:38:28
User entered empty.	System	13 Oct 2020 15:54:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
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.	(b) (4) Coder Import (b) (4)	29 Apr 2021 20:56:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:56:10
Data point term sent to Coder	System	29 Apr 2021 20:54:53
User entered 'Zofran'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 20:54:27

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Nausea prophylaxis'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '2'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'once (ONCE)'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 20:54:27

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 20:54:27
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:54:27

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:54:27

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:54:27

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 05:16:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:16:18
Data point term sent to Coder	System	29 Apr 2021 20:58:58
User entered 'Morphine'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 20:58:17

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Multiple pelvic fractures, R ribs 4-8 fractures'	(b) (4) Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 20:58:17

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '4'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 20:58:17
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:58:17

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:58:17

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:58:17

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
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.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:05:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:05:07
Data point term sent to Coder	System	29 Apr 2021 21:04:19
User entered 'Tylenol'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:03:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Multiple pelvic fractures, R ribs 4-8 fractures'	(b) (4) Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:03:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '1000'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'once (ONCE)'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:03:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:03:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:03:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:03:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
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.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:08:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:08:13
Data point term sent to Coder	System	29 Apr 2021 21:07:23
User entered 'Zofran'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:06:59

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Nausea prophylaxis'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '4'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:06:59
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:06:59

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:06:59

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:06:59

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 23:04:09
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 Apr 2021 23:04:09
Data point term sent to Coder	System	29 Apr 2021 21:19:29
User entered 'Cyclobenzaprine'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:18:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Multiple pelvic fractures, R ribs 4-8 fractures'	(b) (4) Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:18:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '10'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:18:55
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:18:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:18:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:18:55

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:53:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:53:20
Data point term sent to Coder	System	29 Apr 2021 21:51:49
Data point term sent to Coder	System	29 Apr 2021 21:20:30
User entered 'Iopamidol'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:20:19

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'CT CONTRAST' reason for change: Data Entry Error	Ashley Bragg (b) (4)	29 Apr 2021 21:51:14
	(b) (4)	
User entered 'MRI contrast'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '100'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mL (mL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:20:19
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:20:19

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:20:19

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:20:19

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: ARTIFICIAL TEARS [UMBRELLA TERM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Apr 2021 03:59:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 03:59:15
Data point term sent to Coder	System	29 Apr 2021 21:22:37
User entered 'Artificial tears'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:22:07

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Bilateral dry eyes'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '2'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Other (OTHER)'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'drops'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Intraocular (INTRAOCULAR)'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'UN UNK 2019'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:22:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:22:07

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:22:07

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:22:07

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:26:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:26:01
Data point term sent to Coder	System	29 Apr 2021 21:24:37
User entered 'Flonase'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:23:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Seasonal allergies'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '50'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'ug (ug)'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'UN UNK 2000'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:23:43
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:23:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:23:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:23:43

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:27:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:27:01
Data point term sent to Coder	System	29 Apr 2021 21:25:38
User entered 'Miralax'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:25:01

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Constipation prophylaxis'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '17'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'g (g)'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'once daily (QD)'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '26 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:25:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:25:01

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:25:01

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 21:25:01

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:29:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:29:17
Data point term sent to Coder	System	29 Apr 2021 21:27:39
User entered 'Lactated ringers'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:27:03

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'dehydration prophylaxis'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '1000'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mL (mL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'once (ONCE)'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:27:03

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:27:03
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:27:03

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:27:03

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:27:03

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 06:14:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:14:29
Data point term sent to Coder	System	29 Apr 2021 21:35:41
User entered 'Sodium Chloride'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:34:51

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Medication flush'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '20'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mL (mL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'once (ONCE)'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:34:51
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:34:51

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:34:51

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:34:51

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 12:12:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 12:12:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:04:09
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 Apr 2021 23:04:09
Data point term sent to Coder	System	29 Apr 2021 21:36:42
User entered 'Bisacodyl'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:36:36

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Constipation prophylaxis'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '10'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Rectal (RECTAL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '26 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:36:36
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:36:36

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:36:36

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:36:36

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 23:06:10
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 Apr 2021 23:06:10
Data point term sent to Coder	System	29 Apr 2021 21:38:43
User entered 'Docusate'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:38:02

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Constipation prophylaxis'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '283'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Rectal (RECTAL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '26 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:38:02
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:38:02

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:38:02

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:38:02

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE;SENNA ALEXANDRINA, PRODUCTSYNONYM: DOCUSATE;SENNA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:41:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 21:41:08
Data point term sent to Coder	System	29 Apr 2021 21:39:43
User entered 'Docusate-senna'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Constipation prophylaxis'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '50-8.6'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'twice daily (BID)'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '26 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:39:33
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 21:39:33

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:39:33

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 21:39:33

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 05:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:07:29
Data point term sent to Coder	System	29 Apr 2021 21:44:46
User entered 'Lovenox'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:44:07

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Clotting prophylaxis'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '40'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'twice daily (BID)'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '26 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:44:07
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 21:44:07

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:44:07

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 21:44:07

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 04:31:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 04:31:19
Data point term sent to Coder	System	29 Apr 2021 21:46:46
User entered 'Hydrocodone-Acetaminophen'	Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:46:01

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Multiple pelvis fractures, R ribs 4-8 fractures'	(b) (4) Ashley Bragg (b) (4) (b) (4)	29 Apr 2021 21:46:01

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '5-325'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'mg (mg)'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'as needed (PRN)'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '26 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	29 Apr 2021 21:46:01
	(b) (4)	

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:46:01

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:46:01

US3332059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:46:01

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:05:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:27
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
Signature has been broken.	(b) (4)	
	Ashley Bragg (b) (4)	03 Mar 2021 18:48:54
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Ashley Bragg (b) (4)	03 Mar 2021 18:48:54
	(b) (4)	
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:33:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 00:57:58

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:05:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
	(b) (4)	
User entered '2 Mar 2021'	Ashley Bragg (b) (4)	03 Mar 2021 18:49:31
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:05:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
	(b) (4)	
User entered 'Nasal cauterization'	Ashley Bragg (b) (4)	03 Mar 2021 18:49:31
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
	(b) (4)	
User entered 'Adverse Event (AE)'	Ashley Bragg (b) (4)	03 Mar 2021 18:49:31
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:05:08

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:11:30
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	03 Mar 2021 18:49:31
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:49:44
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'CT scan cervical spine'	Ashley Bragg (b) (4)	29 Apr 2021 21:49:44
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Adverse Event (AE)'	Ashley Bragg (b) (4)	29 Apr 2021 21:49:44
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:08

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:49:44
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	Ashley Bragg (b) (4)	29 Apr 2021 21:50:11
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Ct scan thorax'	Ashley Bragg (b) (4)	29 Apr 2021 21:50:11
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'Adverse Event (AE)'	Ashley Bragg (b) (4)	29 Apr 2021 21:50:11
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:08

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	29 Apr 2021 21:50:11
	(b) (4)	

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:05:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 22:32:17

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:05:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'CT SCAN CERVICAL SPINE'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:32:17

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:32:17

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:05:08

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:32:17

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:05:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered '22 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 22:32:37

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:05:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered 'CT SCAN THORAX'	(b) (4), (b) (6)	29 Apr 2021 22:32:37

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:32:37

US3332059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:05:08

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:32:37

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'USA-US202-2021-MRNA-1273-P301000006'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'Yes (Y)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'No (N)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'No (N)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'Yes (Y)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'Yes (Y)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'No (N)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'No (N)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'James'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'Peterson'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'US'	(b) (4) System	30 Apr 2021 14:48:32

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 14:48:32

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'USA-US202-2021-MRNA-1273-P301000006'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'Yes (Y)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'No (N)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'No (N)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'Yes (Y)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'Yes (Y)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'No (N)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'No (N)'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'James'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:19
User entered 'Peterson'	System	30 Apr 2021 14:46:15

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'US'	(b) (4) System	30 Apr 2021 14:48:32

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 14:48:32

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:05:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered '30/Apr/2021 09:48'	(b) (4) System	30 Apr 2021 14:48:32

US3332059

Folder: SAE USA-US202-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:05:08

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.	James Peterson (b) (4)	03 May 2021 14:45:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:48:32