

US3012098 (Prod: Benchmark Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:42:01

All time stamps listed in this document are displayed in GMT

US3012098

Form: Participant Creation

Generated On: 26 Nov 2020 08:42:01

[Participant ID](#)

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

US3012098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

Generated On: 26 Nov 2020 08:42:01

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	60
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

Generated On: 26 Nov 2020 08:42:01

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 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 checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:42:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:42:01

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

Condition	LYRICA ALLERGY
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

Condition	LITHIUM ALLERGY
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

Condition	KEFLEX ALLERGY
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

Condition	SEASONAL ALLERGIES
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: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

Condition	GERD
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: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

Condition	HEARTBURN
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: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

Condition	DIVERTICULITIS
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 (8)

Generated On: 26 Nov 2020 08:42:01

Condition	OBESITY
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 (9)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

Condition	DEPRESSION
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: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

Condition	ANXIETY
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: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

Condition	PANIC ATTACKS
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: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

Condition	INSOMNIA
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: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

Condition	BACK PAIN LUMBAR REGION
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: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

Condition	FIBROMYALGIA
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: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

Condition	UMBILICAL HERNIA
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

Condition	BIPOLAR DISORDER
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: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

Condition	COPD
Start date (dd MMM yyyy)	UN MAR 2018
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)	MAR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:27 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:27
Height (<i>xxx.x</i>)	62.0 in
Weight (<i>xxx.x</i>)	182.6 lb
BMI (<i>xxx.x</i>)	33.46781 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)	

US3012098

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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

Generated On: 26 Nov 2020 08:42:01

Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2004
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Other	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

Generated On: 26 Nov 2020 08:42:01

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 143598

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

Generated On: 26 Nov 2020 08:42:01

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

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)	10 AUG 2020
Time of assessment (00:00-23:59)	17:27 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:27
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)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

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)	10 AUG 2020
Time of assessment (00:00-23:59)	19:46 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 19:46
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Yes ☐
No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	10 AUG 2020
What was the treatment time? (00:00-23:59)	19:13 (24 HR)
Treatment Date and Time (derived)	10 AUG 2020 19:13
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 08:42:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 AUG 2020
Collection time (<i>00:00-23:59</i>)	18:06 (24 HR)
Collection date and time (derived)	10 AUG 2020 18:06

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:42:01

Collection date (<i>dd MMM yyyy</i>)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:33	10 AUG 2020 18:33
Nasopharyngeal Swab 2	No		

US3012098

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 10 AUG 2020 19:46

PC Open Date & Time 10 AUG 2020 19:33

PC Close Date & Time 10 AUG 2020 22:03

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 10 AUG 2020 22:58

PC Close Date & Time 11 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 13:36

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

98.3 °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

12 AUG 2020 17:31

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 19:04

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 18:13

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 18:43

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 23:45

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

10 AUG 2020 19:47

PC Open Date & Time

10 AUG 2020 19:33

PC Close Date & Time

10 AUG 2020 22:03

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 AUG 2020 22:58

PC Close Date & Time

11 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

11 AUG 2020 13:36

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

12 AUG 2020 17:32

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

13 AUG 2020 19:04

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

14 AUG 2020 18:14

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

15 AUG 2020 18:44

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

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

16 AUG 2020 23:46

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 19:47
PC Open Date & Time	10 AUG 2020 19:33
PC Close Date & Time	10 AUG 2020 22:03

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 22:58

PC Close Date & Time

11 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 13:37
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 17:33
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 19:05
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 18:15
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 18:45
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 23:47
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3012098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

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)	08 SEP 2020
Time of assessment (00:00-23:59)	07:23 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 07:23
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

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)	08 SEP 2020
Time of assessment (00:00-23:59)	09:24 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:24
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3012098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 08:44 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 08:44

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

US3012098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	08 SEP 2020
Collection time (<i>00:00-23:59</i>)	07:55 (24 HR)
Collection date and time (derived)	08 SEP 2020 07:55

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:42:01

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:42	08 SEP 2020 07:42
Nasopharyngeal Swab 2	No		

US3012098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

08 SEP 2020 09:21

PC Open Date & Time

08 SEP 2020 09:04

PC Close Date & Time

08 SEP 2020 11:34

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

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 98.2 °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	08 SEP 2020 19:45
PC Open Date & Time	08 SEP 2020 12:29
PC Close Date & Time	09 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 17:52

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

97.1 °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

10 SEP 2020 19:54

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

98.6 °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

11 SEP 2020 19:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:21

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

13 SEP 2020 17:40

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

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**

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 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 09:21

PC Open Date & Time

08 SEP 2020 09:04

PC Close Date & Time

08 SEP 2020 11:34

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:46

PC Open Date & Time

08 SEP 2020 12:29

PC Close Date & Time

09 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 17:55

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

10 SEP 2020 19:55

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

11 SEP 2020 19:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

12 SEP 2020 21:22

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

13 SEP 2020 17:40

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 09:22
PC Open Date & Time	08 SEP 2020 09:04
PC Close Date & Time	08 SEP 2020 11:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 19:47
PC Open Date & Time	08 SEP 2020 12:29
PC Close Date & Time	09 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 17:56
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:55
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:23
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

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 ☒

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:41
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:15 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 15:15
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

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.

US3012098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	16:00 (24 HR)
Collection date and time (derived)	13 OCT 2020 16:00

US3012098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 18:09:07

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

17 OCT 2020 02:45:18

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

28 OCT 2020 19:49:41

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 18:00:56

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

11 OCT 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 103

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 138

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 159

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 215

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01
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Patient Cloud Close Date & Time	28 MAR 2021 23:59
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US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	15 AUG 2021 23:59
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US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	22 AUG 2021 23:59
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US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	05 DEC 2021 23:59
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US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	24 APR 2022 23:59
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US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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="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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 <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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3012098

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:42:01

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"/>

US3012098

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:42:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 08:42:01

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	SICKD1

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:34 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 09:34
Height (<i>xxx.x</i>)	62.5 in
Weight (<i>xxx.x</i>)	166.2 lb
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	105 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012098

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

US3012098

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:42:01

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 AUG 2020

US3012098

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Visit date (dd MMM yyyy)	
--------------------------	--

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

Folder OID	SICKD28
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US3012098

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	<input type="text"/>
Time of assessment (<i>00:00-23:59</i>)	<input type="text"/>
Vital Signs Date and Time (derived)	<input type="text"/>
Temperature (<i>xxx.x</i>)	<input type="text"/>
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	<input type="text"/>
Pulse (<i>xxx</i>)	<input type="text"/>
Pulse units	<input type="text"/>
Respiratory Rate (<i>xxx</i>)	<input type="text"/>
Respiratory Rate units	<input type="text"/>
Systolic Blood Pressure (<i>xxx</i>)	<input type="text"/>
Systolic Blood Pressure units	<input type="text"/>
Diastolic Blood Pressure (<i>xxx</i>)	<input type="text"/>
Diastolic Blood Pressure units	<input type="text"/>
Height (derived)	<input type="text"/>
Weight (derived)	<input type="text"/>

US3012098

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3012098

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:42:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3012098

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:42:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

AEID	USA-US006-2020-MRNA-1273-P30 1000002
Adverse event	COLITIS
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)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	12 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

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	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	PATIENT REPORTED TO ER ON 26-SEP-2020 WITH SEVERE ABDOMINAL PAIN, GENERAL/ENTIRE AREA. WAS ADMITTED AND GIVEN UNKNOWN MEDICATIONS FOR PAIN. NO DIAGNOSIS AS OF YET.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

AEID	USA-US006-2020-MRNA-1273-P30 1000002
Adverse event	CLOSTRICFIUM DIFFICILE
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)	29 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	12 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	5

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

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	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	SUBJECT WAS ADMITTED TO HOSPITAL ON 29-SEP-2020 DUE TO ABDOMINAL PAIN, WAS DIAGNOSED WITH C-DIFF 5 DAYS LATER, TREATED AND RELEASED ON 12-OCT-2020.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

AEID	USA-US006-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE HYPOXIC RESPIRATORY FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	29 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	12 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

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	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	SUBJECT REPORTED TO ER WITH ABDOMINAL PAIN. DURING COURSE OF HOSPITALIZATION, SUBJECT EXPERIENCED ACUTE HYPOXIC RESPIRATORY FAILURE. UNKNOWN WHAT DATE THIS OCCURRED OR HOW LONG IT LASTED.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

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)

Generated On: 26 Nov 2020 08:42:01

AEID	USA-US006-2020-MRNA-1273-P30 1000002
Adverse event	EXACERBATION OF DIASTOLIC CHF
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)	29 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	12 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

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	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	SUBJECT REPORTED TO ER WITH ABDOMINAL PAIN. DURING COURSE OF HOSPITALIZATION, SUBJECT EXPERIENCED AN EXACERBATION OF CONGESTIVE HEART FAILURE. UNKNOWN WHAT DATE THIS OCCURRED OR HOW LONG IT LASTED.

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:42:01

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)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	ALBUTEROL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	EMPHYSEMA
Dose per administration	90
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
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 (2)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	ABILIFY
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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 (4)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	CLONIDINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY, HYPERTENSION
Dose per administration	100
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	DEXILANT
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIVERTICULITIS
Dose per administration	60
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	DOXEPIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	300
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	FISH OIL
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

	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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	FLONASE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SEASONAL ALLERGIES
Dose per administration	50
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
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 (9)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	GLUCOSAMINE CHONDROITIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

	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 (10)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	HYDROCODONE/APAP
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	OSTEOARTHRITIS
Dose per administration	10/325
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input checked="" type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	ASTELIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	EMPHYSEMA
Dose per administration	137
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	HYDROXYZINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	INSOMNIA
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

	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 2018	
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	IRON
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	LAMOTRIGINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BIPOLAR DISORDER
Dose per administration	25
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

	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 2018
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	100
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

	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 2018	
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	METOPROLOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERTENSION
Dose per administration	25
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	MONTELUKAST
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SEASONAL ALLERGIES
Dose per administration	20
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	TOPIRAMATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FIBROMYALGIA
Dose per administration	200
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	TRINTELLIX
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DEPRESSION
Dose per administration	20
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	VANCOMYCIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	C-DIFF
Dose per administration	125
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
<hr/>		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	DICYCLOMINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	COLITIS (AE #1)
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

	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)		29 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)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	ONDASETRON
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NAUSEA
Dose per administration	4
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	Q6H/PRN Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	BENZOCCINE 20%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CRACKED TONGUE , FEVER BLISTER
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

	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)		10 OCT 2020
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	DIMETHICONE 1.5%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BODY ACHES/WEAKNESS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (<i>dd MMM yyyy</i>)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	FUROSEMIDE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIURETIC, FROM HOSPITALIZATION
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input checked="" type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input checked="" type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	METRONIDAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	UTI TREATMENT PART OF HOSPITALIZATION
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

	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)		29 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)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	MORPHINE SULFATE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN IN ABDOMEN PART OF HOSPITALIZATION
Dose per administration	4
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	METRONIDAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	UTI TREATMENT PRE-EMPTIVE PART OF HOSPITALIZATION
Dose per administration	100
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	Q6H Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	PANTOPRAZOLE SODIUM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GERD DURING HOSPITALIZATION
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 12 OCT 2020		
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	PANTOPRAZOLE SODIUM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GERD DURING HOSPITALIZATION
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

	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)		29 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)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	POLYETHYLENE GLYCOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN IN ABDOMEN DX COLITIS
Dose per administration	17
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input checked="" type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		12 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	TRAMADOL HCL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PAIN IN ABDOMEN DX COLITIS DURING HOSPITALIZATION
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	VILANTEROL/UMECLIDINIUM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COPD- DURING HOSPITALIZATION
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input checked="" type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
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"/>	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	VORTIOXETINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION - DURING HOSPITALIZATION
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 12 OCT 2020		
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	INFLUENZA PREVENTION
Dose per administration	0.5
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input checked="" type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	SHINGLES VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SHINGLES PREVENTION
Dose per administration	05
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	MYRBETRIQ
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	OVERACTIVE BLADDER
Dose per administration	25
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

	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)		03 NOV 2020
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"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

Name of Medication	DICYCLOMINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	COLITIS PREVENTION
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

	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)		13 OCT 2020
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"/>

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:42:01

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:42:01

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 SEP 2020	CHEST CT FOR PULMONARY EMBOLUS, NEGATIVE	Adverse Event	
14 OCT 2020	SARS-COV-2 TEST (NASAL, NEGATIVE)	Adverse Event	
29 SEP 2020	GI PANEL- BACTERIA PCR - NEGATIVE	Diagnostic	
30 SEP 2020	CHEST CT FOR PULMONARY EMBOLUS, NEGATIVE	Adverse Event	
29 SEP 2020	CT SCAN - ABDOMEN/PELVIS FOR DIAGNOSIS, NORMAL	Adverse Event	
30 SEP 2020	TRANSTHORACIC ECHOCARDIOGRAPH	Adverse Event	
29 SEP 2020	ELECTROCARDIOGRAM	Adverse Event	

US3012098

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:42:01

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

US3012098

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:42:01

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 ☐

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	12/OCT/2020 15:58
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

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	14/OCT/2020 13:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	21/OCT/2020 12:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	30/OCT/2020 09:58
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

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	02/NOV/2020 15:22
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

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	04/NOV/2020 09:12
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

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	06/NOV/2020 12:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/NOV/2020 16:58
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

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	19/NOV/2020 11:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 08:42:01

SAEID	USA-US006-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	19/NOV/2020 12:47
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

US3012098 (Prod: Benchmark Research)

US3012098

Form: Participant Creation

Generated On: 26 Nov 2020 08:42:01

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3012098'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Aug 2020 22:34:18

US3012098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:47

US3012098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 22:34:19

US3012098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:47

US3012098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 00:32:47

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 22:34:20

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Age](#)

Audit	User	Time (GMT)
User entered '60'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '60'	System	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[White](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:42:01

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 22:34:19

US3012098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 00:33:10

US3012098

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:42:01

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:10

US3012098

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:42:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:08:30

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:59:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:59:52
Data point term sent to Coder	System	11 Aug 2020 01:09:38
User entered 'lyrica allergy'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '1999'	System	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:08:51

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:39:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:39:58
Data point term sent to Coder	System	11 Aug 2020 01:09:38
User entered 'lithium allergy'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '1999'	System	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:09:11

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
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) (b) (4)	14 Aug 2020 17:09:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:09:24
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) (b) (4)	11 Aug 2020 01:10:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:10:19
Data point term sent to Coder	System	11 Aug 2020 01:09:38
User entered 'keflex allergy'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '1999'	System	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:09:31

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	11 Aug 2020 01:12:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:12:22
Data point term sent to Coder	System	11 Aug 2020 01:10:38
User entered 'seasonal allergies'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:09:57

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:12:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:12:23
Data point term sent to Coder	System	11 Aug 2020 01:10:39
User entered 'GERD'	(b) (4), (b) (6)	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:10:32

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:13:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:13:26
Data point term sent to Coder	System	11 Aug 2020 01:12:42
User entered 'heartburn'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:11:50

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:13:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:13:26
Data point term sent to Coder	System	11 Aug 2020 01:12:40
User entered 'diverticulitis'	(b) (4), (b) (6)	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2010'	System	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:12:21

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:28
Data point term sent to Coder	System	11 Aug 2020 01:13:42
User entered 'obesity'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	(b) (4), (b) (6)	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '1980'	System	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:12:50

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:29
Data point term sent to Coder	System	11 Aug 2020 01:13:42
User entered 'hypothyroidism'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '1990'	System	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:13:14

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:14:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:14:28
Data point term sent to Coder	System	11 Aug 2020 01:13:42
User entered 'menopause'	(b) (4), (b) (6)	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	(b) (4), (b) (6)	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2005'	System	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:13:36

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:15:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:15:17
Data point term sent to Coder	System	11 Aug 2020 01:14:43
User entered 'overactive bladder'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	(b) (4), (b) (6)	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2005'	System	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:14:22

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:16:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:16:24
Data point term sent to Coder	System	11 Aug 2020 01:15:43
User entered 'hypertension'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:14:52

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	11 Aug 2020 01:16:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:16:24
Data point term sent to Coder	System	11 Aug 2020 01:15:43
User entered 'hypercholesterolemia'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:15:15

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:17:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:17:25
Data point term sent to Coder	System	11 Aug 2020 01:16:44
User entered 'emphysema'	(b) (4), (b) (6)	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:15:48

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:11
Data point term sent to Coder	System	11 Aug 2020 01:16:44
User entered 'depression'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:16:19

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
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)	11 Aug 2020 01:18:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:18:26
Data point term sent to Coder	System	11 Aug 2020 01:17:44
User entered 'anxiety'	(b) (4), (b) (6)	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:16:44

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Panic attacks and disorders, PT: Panic attack, LLT: Panic attacks - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:18:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	11 Aug 2020 01:18:26
Data point term sent to Coder	System	11 Aug 2020 01:17:44
User entered 'panic attacks'	(b) (4), (b) (6)	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:17:06

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:18:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 01:18:26
Data point term sent to Coder	System	11 Aug 2020 01:17:45
User entered 'insomnia'	(b) (4), (b) (6)	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:17:37

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:36:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:36:12
Data point term sent to Coder	System	11 Aug 2020 01:18:47
User entered 'osteoarthritis (lower back, lower neck)'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2010'	System	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:18:23

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 06:42:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 06:42:23
Data point term sent to Coder	System	11 Aug 2020 01:19:50
User entered 'BACK PAIN LUMBaR REGION' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 01:18:59
User entered 'back pain lumber region'	(b) (4), (b) (6)	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:18:52

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:20:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:20:27
Data point term sent to Coder	System	11 Aug 2020 01:19:50
User entered 'fibromyalgia'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:19:28

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:21:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:21:16
Data point term sent to Coder	System	11 Aug 2020 01:20:51
User entered 'umbilical hernia'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '1997'	System	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:20:19

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 01:23:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	03 Oct 2020 01:23:53
Data point term sent to Coder	System	03 Oct 2020 01:23:09
User entered 'BIPOLAR DISORDER'	Lamar Box (b) (4)	03 Oct 2020 01:22:31
	(b) (4)	

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2000'	System	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 01:22:31

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis. Update eCRF as appropriate, or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:24:09
Query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis. Update eCRF as appropriate, or provide clarification. ' answered with 'COPD and Emphysema are two separate conditions.' (Site from DM).	Jennifer Leyva (b) (4)	23 Oct 2020 16:09:03
User opened query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis. Update eCRF as appropriate, or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:42:02
Query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis instead of separate symptoms. Update eCRF as appropriate, or provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:41:35
User opened query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis instead of separate symptoms. Update eCRF as appropriate, or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:41:27

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 19:18:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 19:18:45
Data point term sent to Coder	System	14 Oct 2020 19:17:40
User entered 'COPD'	Jennifer Leyva (b) (4)	14 Oct 2020 19:16:44
	(b) (4)	

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'UN Mar 2018'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Mar 2018'	System	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2018'	System	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:16:44

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:05:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:05:00
Data point term sent to Coder	System	18 Nov 2020 21:19:41
User entered 'Diastolic Congestive Heart Failure'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '2019'	System	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:19:07

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '17:27'	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 17:27'	System	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '62.0' in	(b) (4), (b) (6)	11 Aug 2020 01:21:27
DataPoint set to visible.	System	11 Aug 2020 00:33:10

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '182.6' lb	(b) (4), (b) (6)	11 Aug 2020 01:21:27
DataPoint set to visible.	System	11 Aug 2020 00:33:10

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '33.46781'	System	16 Sep 2020 23:50:57
User entered '33.5'	System	11 Aug 2020 01:21:27
DataPoint set to visible.	System	11 Aug 2020 00:33:10

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Aug 2020 01:21:27
DataPoint set to visible.	System	11 Aug 2020 00:33:10

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:09
User entered '98.4' F	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:09
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:09
User entered '92'	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:09
User entered '12'	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:09
User entered '106'	(b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:09
User entered '88'	(b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 01:21:27

US3012098

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:22:15

US3012098

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 09:47:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 13:13:43
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:22:22
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:22:22
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 01:22:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:22:15
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:22:15
User entered '10 Apr 2020'	(b) (4), (b) (6)	11 Aug 2020 01:22:15

US3012098

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:23:46

US3012098

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:01

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:23:46

US3012098

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:01

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	11 Aug 2020 01:23:46

US3012098

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:01

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:23:46

US3012098

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:23:46

US3012098

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:01

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:23:46

US3012098

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 08:26:10
Query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' answered with 'Per PI, postmenopausal status is reached once without menses for one year.' (Site from DM).	Jennifer Leyva (b) (4)	27 Aug 2020 14:10:12
User opened query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 11:27:31
User entered 'un UNK 2004'	(b) (4), (b) (6)	11 Aug 2020 01:23:46

US3012098

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:01

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:23:46

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Other

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:01

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:25:02

US3012098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:25:02

US3012098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 01:25:02

US3012098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 01:25:02

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Aug 2020 23:44:16

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:27:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:27:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 23:44:16
User entered '143598' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 23:44:16

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 23:44:16

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:01

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:04:27
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	28 Oct 2020 14:12:36
User entered 'No (N)'	Jennifer Leyva (b) (4)	28 Oct 2020 14:12:34
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:49:56
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:24:17

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '17:27'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 17:27'	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.'	System	11 Aug 2020 01:27:09
(Site from System).		
Query 'Data is required. Please provide.' answered by System		11 Aug 2020 01:27:09
data change (Site from System).		
User entered '92' reason for change: Data Entry	(b) (4), (b) (6)	11 Aug 2020 01:27:09
Error		
User opened query 'Data is required. Please provide.'	System	11 Aug 2020 01:26:46
(Site from System).		
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 01:27:09
User entered empty.	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Aug 2020 01:27:09
User entered '12' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	11 Aug 2020 01:27:09
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) [REDACTED]	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 01:27:09
User entered empty.	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Aug 2020 01:27:09
User entered '106' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	11 Aug 2020 01:27:09
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) [REDACTED]	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 01:27:09
User entered empty.	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.'	System	11 Aug 2020 01:27:09
(Site from System).		
Query 'Data is required. Please provide.' answered by System		11 Aug 2020 01:27:09
data change (Site from System).		
User entered '88' reason for change: Data Entry	(b) (4), (b) (6)	11 Aug 2020 01:27:09
Error		
User opened query 'Data is required. Please provide.'	System	11 Aug 2020 01:26:46
(Site from System).		
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 01:27:09
User entered empty.	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 10:42:08
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post dose vitals are collected 30 minutes post vaccination.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 01:27:37
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 01:26:46
User entered '19:46'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:46'	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Aug 2020 01:27:57
User entered '82' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 01:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 01:27:57
User entered empty.	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Aug 2020 01:27:57
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	11 Aug 2020 01:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) [REDACTED]	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 01:27:57
User entered empty.	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Aug 2020 01:27:57
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	11 Aug 2020 01:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) [REDACTED]	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 01:27:57
User entered empty.	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Aug 2020 01:27:57
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 01:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 01:27:57
User entered empty.	System	11 Aug 2020 01:26:46

US3012098

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	08 Sep 2020 13:18:43
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	08 Sep 2020 13:18:36
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:28:09

US3012098

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Jennifer Leyva (b) (4)	08 Sep 2020 13:18:43
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:28:09

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '19:13'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:13'	System	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 00:33:30

US3012098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:29:06

US3012098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:29:06

US3012098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '18:06'	(b) (4), (b) (6)	11 Aug 2020 01:29:06

US3012098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 18:06'	System	11 Aug 2020 01:29:06

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:42:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:42:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:42:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:42:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '18:33'	(b) (4), (b) (6)	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:42:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 18:33'	System	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:42:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:42:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:42:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:42:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:29:36

US3012098

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:29:43

US3012098

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 01:29:43

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '6be01292-0f1d-4b31-8e1b-69b2ab4ef969'	System	11 Aug 2020 00:46:33
User entered 'Yes (Y)'	System	11 Aug 2020 00:46:33

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '6be01292-0f1d-4b31-8e1b-69b2ab4ef969'	System	11 Aug 2020 00:46:33
User entered '98.1'	System	11 Aug 2020 00:46:33

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:13', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '6be01292-0f1d-4b31-8e1b-69b2ab4ef969'	System	11 Aug 2020 00:46:33
User entered 'No (N)'	System	11 Aug 2020 00:46:33

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:24', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '6be01292-0f1d-4b31-8e1b-69b2ab4ef969'	System	11 Aug 2020 00:46:33
User entered '10 Aug 2020 19:46'	System	11 Aug 2020 00:46:33

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:33'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:03'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:58'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 2'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:35:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9c20e064-d651-448a-9cea-efa369ef8677'	System	11 Aug 2020 18:36:14
User entered 'Yes (Y)'	System	11 Aug 2020 18:36:14

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:35:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9c20e064-d651-448a-9cea-efa369ef8677'	System	11 Aug 2020 18:36:14
User entered '98.7'	System	11 Aug 2020 18:36:14

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:35:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9c20e064-d651-448a-9cea-efa369ef8677'	System	11 Aug 2020 18:36:14
User entered 'No (N)'	System	11 Aug 2020 18:36:14

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9c20e064-d651-448a-9cea-efa369ef8677'	System	11 Aug 2020 18:36:14
User entered '11 Aug 2020 13:36'	System	11 Aug 2020 18:36:14

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 3'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:31:20', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '57947b7e-c952-4fb3-ae30-0dc67b322eba'	System	12 Aug 2020 22:31:53
User entered 'Yes (Y)'	System	12 Aug 2020 22:31:53

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:31:28', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '57947b7e-c952-4fb3-ae30-0dc67b322eba'	System	12 Aug 2020 22:31:53
User entered '98.3'	System	12 Aug 2020 22:31:53

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:31:34', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '57947b7e-c952-4fb3-ae30-0dc67b322eba'	System	12 Aug 2020 22:31:53
User entered 'No (N)'	System	12 Aug 2020 22:31:53

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:31:49', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '57947b7e-c952-4fb3-ae30-0dc67b322eba'	System	12 Aug 2020 22:31:53
User entered '12 Aug 2020 17:31'	System	12 Aug 2020 22:31:53

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 4'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:03:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd3dd55d9-e095-4a4e-983a-fb0bd4840993'	System	14 Aug 2020 00:04:12
User entered 'Yes (Y)'	System	14 Aug 2020 00:04:12

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:03:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd3dd55d9-e095-4a4e-983a-fb0bd4840993'	System	14 Aug 2020 00:04:12
User entered '97.0'	System	14 Aug 2020 00:04:12

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd3dd55d9-e095-4a4e-983a-fb0bd4840993'	System	14 Aug 2020 00:04:12
User entered 'No (N)'	System	14 Aug 2020 00:04:12

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd3dd55d9-e095-4a4e-983a-fb0bd4840993'	System	14 Aug 2020 00:04:12
User entered '13 Aug 2020 19:04'	System	14 Aug 2020 00:04:12

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 5'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:13:35', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'e8503204-5113-4292-90d3-1031f7c7edaa'	System	14 Aug 2020 23:13:54
User entered 'Yes (Y)'	System	14 Aug 2020 23:13:54

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:13:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'e8503204-5113-4292-90d3-1031f7c7edaa'	System	14 Aug 2020 23:13:54
User entered '97.9'	System	14 Aug 2020 23:13:54

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:13:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'e8503204-5113-4292-90d3-1031f7c7edaa'	System	14 Aug 2020 23:13:54
User entered 'No (N)'	System	14 Aug 2020 23:13:54

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:13:52', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'e8503204-5113-4292-90d3-1031f7c7edaa'	System	14 Aug 2020 23:13:54
User entered '14 Aug 2020 18:13'	System	14 Aug 2020 23:13:54

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 6'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '40da028d-c99a-42fe-838f-52029b1aa586'	System	15 Aug 2020 23:43:43
User entered 'Yes (Y)'	System	15 Aug 2020 23:43:43

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:28', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '40da028d-c99a-42fe-838f-52029b1aa586'	System	15 Aug 2020 23:43:43
User entered '96.8'	System	15 Aug 2020 23:43:43

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:32', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '40da028d-c99a-42fe-838f-52029b1aa586'	System	15 Aug 2020 23:43:43
User entered 'No (N)'	System	15 Aug 2020 23:43:43

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:39', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '40da028d-c99a-42fe-838f-52029b1aa586'	System	15 Aug 2020 23:43:43
User entered '15 Aug 2020 18:43'	System	15 Aug 2020 23:43:43

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 7'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:25', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9fb0d092-0ef5-4079-b1f0-7cda3d1701a1'	System	17 Aug 2020 04:45:55
User entered 'Yes (Y)'	System	17 Aug 2020 04:45:55

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9fb0d092-0ef5-4079-b1f0-7cda3d1701a1'	System	17 Aug 2020 04:45:55
User entered '96.8'	System	17 Aug 2020 04:45:55

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9fb0d092-0ef5-4079-b1f0-7cda3d1701a1'	System	17 Aug 2020 04:45:55
User entered 'No (N)'	System	17 Aug 2020 04:45:55

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9fb0d092-0ef5-4079-b1f0-7cda3d1701a1'	System	17 Aug 2020 04:45:55
User entered '16 Aug 2020 23:45'	System	17 Aug 2020 04:45:55

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered 'None (1)'	System	11 Aug 2020 00:47:12

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:49', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered 'No (N)'	System	11 Aug 2020 00:47:12

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:52', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered 'No (N)'	System	11 Aug 2020 00:47:12

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:58', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered 'None (1)'	System	11 Aug 2020 00:47:12

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered '10 Aug 2020 19:47'	System	11 Aug 2020 00:47:12

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:33'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:03'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:58'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 2'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **PAIN AT INJECTION SITE.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered 'None (1)'	System	11 Aug 2020 18:36:50

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:23', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered 'No (N)'	System	11 Aug 2020 18:36:50

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:27', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered 'No (N)'	System	11 Aug 2020 18:36:50

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:32', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered 'None (1)'	System	11 Aug 2020 18:36:50

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered '11 Aug 2020 13:36'	System	11 Aug 2020 18:36:50

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 3'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 22:32:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered 'No (N)'	System	12 Aug 2020 22:32:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered 'No (N)'	System	12 Aug 2020 22:32:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:20', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered 'None (1)'	System	12 Aug 2020 22:32:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered '12 Aug 2020 17:32'	System	12 Aug 2020 22:32:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 4'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:15', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered 'None (1)'	System	14 Aug 2020 00:04:47

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered 'No (N)'	System	14 Aug 2020 00:04:47

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:23', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered 'No (N)'	System	14 Aug 2020 00:04:47

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered 'None (1)'	System	14 Aug 2020 00:04:47

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered '13 Aug 2020 19:04'	System	14 Aug 2020 00:04:47

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 5'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:04', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered 'None (1)'	System	14 Aug 2020 23:14:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered 'No (N)'	System	14 Aug 2020 23:14:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:11', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered 'No (N)'	System	14 Aug 2020 23:14:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered 'None (1)'	System	14 Aug 2020 23:14:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:30', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered '14 Aug 2020 18:14'	System	14 Aug 2020 23:14:34

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 6'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **PAIN AT INJECTION SITE.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered 'None (1)'	System	15 Aug 2020 23:44:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:58', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered 'No (N)'	System	15 Aug 2020 23:44:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:03', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered 'No (N)'	System	15 Aug 2020 23:44:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered 'None (1)'	System	15 Aug 2020 23:44:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:17', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered '15 Aug 2020 18:44'	System	15 Aug 2020 23:44:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 7'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **PAIN AT INJECTION SITE.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:57', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered 'None (1)'	System	17 Aug 2020 04:46:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered 'No (N)'	System	17 Aug 2020 04:46:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:04', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered 'No (N)'	System	17 Aug 2020 04:46:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered 'None (1)'	System	17 Aug 2020 04:46:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered '16 Aug 2020 23:46'	System	17 Aug 2020 04:46:22

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:15', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:25', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:30', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'No (N)'	System	11 Aug 2020 00:47:56

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered '10 Aug 2020 19:47'	System	11 Aug 2020 00:47:56

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:33'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:03'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:58'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 2'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:47', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:37:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:37:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:37:11', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'No (N)'	System	11 Aug 2020 18:37:25

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:37:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered '11 Aug 2020 13:37'	System	11 Aug 2020 18:37:25

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 3'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:33:21

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:44', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:56', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:33:03', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:33:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'No (N)'	System	12 Aug 2020 22:33:21

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:33:18', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered '12 Aug 2020 17:33'	System	12 Aug 2020 22:33:21

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 4'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:47', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:10', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:15', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:24', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'No (N)'	System	14 Aug 2020 00:05:39

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered '13 Aug 2020 19:05'	System	14 Aug 2020 00:05:39

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 5'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:43', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:56', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:15:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'No (N)'	System	14 Aug 2020 23:15:14

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:15:11', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered '14 Aug 2020 18:15'	System	14 Aug 2020 23:15:14

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 6'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:25', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:28', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:38', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:48', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:54', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'No (N)'	System	15 Aug 2020 23:45:07

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:45:03', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered '15 Aug 2020 18:45'	System	15 Aug 2020 23:45:07

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 7'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'No (N)'	System	17 Aug 2020 04:47:05

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:47:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered '16 Aug 2020 23:47'	System	17 Aug 2020 04:47:05

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:27

US3012098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:27

US3012098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:27

US3012098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:27

US3012098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:32

US3012098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 14:44:32

US3012098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:52

US3012098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:52

US3012098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:52

US3012098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:52

US3012098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:57

US3012098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Aug 2020 22:07:57

US3012098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:44

US3012098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:44

US3012098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:44

US3012098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:44

US3012098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:50

US3012098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 17:20:50

US3012098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:13:43

US3012098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:13:43

US3012098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:13:43

US3012098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Sep 2020 13:13:43

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '07:23'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 07:23'	System	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 13:16:21

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '09:24'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:24'	System	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 00:35:52

US3012098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:36

US3012098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:36

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:44'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 08:44'	System	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:01

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 14:16:24

US3012098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:00

US3012098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:00

US3012098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '07:55' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	08 Sep 2020 13:17:08
User entered '07:23'	Jennifer Leyva (b) (4)	08 Sep 2020 13:17:00

US3012098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 07:55'	System	08 Sep 2020 13:17:08
User entered '08 Sep 2020 07:23'	System	08 Sep 2020 13:17:00

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:42:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:42:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:42:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:42:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '07:42'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:42:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 07:42'	System	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:42:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:42:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:42:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:42:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 13:17:19

US3012098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:22

US3012098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 13:17:22

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:20:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'eed2fee6-3e65-4e3c-943e-cba6a65eb4f2'	System	08 Sep 2020 14:21:17
User entered 'Yes (Y)'	System	08 Sep 2020 14:21:17

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'eed2fee6-3e65-4e3c-943e-cba6a65eb4f2'	System	08 Sep 2020 14:21:17
User entered '97.7'	System	08 Sep 2020 14:21:17

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'eed2fee6-3e65-4e3c-943e-cba6a65eb4f2'	System	08 Sep 2020 14:21:17
User entered 'No (N)'	System	08 Sep 2020 14:21:17

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'eed2fee6-3e65-4e3c-943e-cba6a65eb4f2'	System	08 Sep 2020 14:21:17
User entered '08 Sep 2020 09:21'	System	08 Sep 2020 14:21:17

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:04'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:34'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:03', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2dd18287-40ac-4d93-9823-8260f181ef3d'	System	09 Sep 2020 00:45:31
User entered 'Yes (Y)'	System	09 Sep 2020 00:45:31

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2dd18287-40ac-4d93-9823-8260f181ef3d'	System	09 Sep 2020 00:45:31
User entered '98.2'	System	09 Sep 2020 00:45:31

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:13', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2dd18287-40ac-4d93-9823-8260f181ef3d'	System	09 Sep 2020 00:45:31
User entered 'No (N)'	System	09 Sep 2020 00:45:31

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:23', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2dd18287-40ac-4d93-9823-8260f181ef3d'	System	09 Sep 2020 00:45:31
User entered '08 Sep 2020 19:45'	System	09 Sep 2020 00:45:31

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 2'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:51:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'daf298f9-f3f0-4e5e-843a-6d44924eeb8e'	System	09 Sep 2020 22:52:12
User entered 'Yes (Y)'	System	09 Sep 2020 22:52:12

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:51:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'daf298f9-f3f0-4e5e-843a-6d44924eeb8e'	System	09 Sep 2020 22:52:12
User entered '98.8'	System	09 Sep 2020 22:52:12

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:52:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'daf298f9-f3f0-4e5e-843a-6d44924eeb8e'	System	09 Sep 2020 22:52:12
User entered 'No (N)'	System	09 Sep 2020 22:52:12

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:52:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'daf298f9-f3f0-4e5e-843a-6d44924eeb8e'	System	09 Sep 2020 22:52:12
User entered '09 Sep 2020 17:52'	System	09 Sep 2020 22:52:12

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 3'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:04', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f06c3f09-f606-4d11-964d-93e6cc1fa6fc'	System	11 Sep 2020 00:54:29
User entered 'Yes (Y)'	System	11 Sep 2020 00:54:29

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f06c3f09-f606-4d11-964d-93e6cc1fa6fc'	System	11 Sep 2020 00:54:29
User entered '97.1'	System	11 Sep 2020 00:54:29

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:17', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f06c3f09-f606-4d11-964d-93e6cc1fa6fc'	System	11 Sep 2020 00:54:29
User entered 'No (N)'	System	11 Sep 2020 00:54:29

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:24', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f06c3f09-f606-4d11-964d-93e6cc1fa6fc'	System	11 Sep 2020 00:54:29
User entered '10 Sep 2020 19:54'	System	11 Sep 2020 00:54:29

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 4'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:23:43', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '50c43d24-61a3-4d5e-bdf7-752594435695'	System	12 Sep 2020 00:24:08
User entered 'Yes (Y)'	System	12 Sep 2020 00:24:08

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:23:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '50c43d24-61a3-4d5e-bdf7-752594435695'	System	12 Sep 2020 00:24:08
User entered '98.6'	System	12 Sep 2020 00:24:08

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:23:54', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '50c43d24-61a3-4d5e-bdf7-752594435695'	System	12 Sep 2020 00:24:08
User entered 'No (N)'	System	12 Sep 2020 00:24:08

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '50c43d24-61a3-4d5e-bdf7-752594435695'	System	12 Sep 2020 00:24:08
User entered '11 Sep 2020 19:24'	System	12 Sep 2020 00:24:08

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 5'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:18', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '8f1eae5-7b06-458a-9189-124ba143e6dd'	System	13 Sep 2020 02:21:52
User entered 'Yes (Y)'	System	13 Sep 2020 02:21:52

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:35', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '8f1eae5-7b06-458a-9189-124ba143e6dd'	System	13 Sep 2020 02:21:52
User entered '96.8'	System	13 Sep 2020 02:21:52

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:39', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '8f1eae5-7b06-458a-9189-124ba143e6dd'	System	13 Sep 2020 02:21:52
User entered 'No (N)'	System	13 Sep 2020 02:21:52

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '8f1eae5-7b06-458a-9189-124ba143e6dd'	System	13 Sep 2020 02:21:52
User entered '12 Sep 2020 21:21'	System	13 Sep 2020 02:21:52

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 6'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '1430dc28-60d1-4579-be2f-2ce4b28717ec'	System	13 Sep 2020 22:40:34
User entered 'Yes (Y)'	System	13 Sep 2020 22:40:34

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '1430dc28-60d1-4579-be2f-2ce4b28717ec'	System	13 Sep 2020 22:40:34
User entered '97.6'	System	13 Sep 2020 22:40:34

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:22', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '1430dc28-60d1-4579-be2f-2ce4b28717ec'	System	13 Sep 2020 22:40:34
User entered 'No (N)'	System	13 Sep 2020 22:40:34

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '1430dc28-60d1-4579-be2f-2ce4b28717ec'	System	13 Sep 2020 22:40:34
User entered '13 Sep 2020 17:40'	System	13 Sep 2020 22:40:34

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 7'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered 'None (1)'	System	08 Sep 2020 14:21:58

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:37', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered 'No (N)'	System	08 Sep 2020 14:21:58

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:41', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered 'No (N)'	System	08 Sep 2020 14:21:58

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered 'None (1)'	System	08 Sep 2020 14:21:58

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered '08 Sep 2020 09:21'	System	08 Sep 2020 14:21:58

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:04'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:34'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 00:46:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered 'No (N)'	System	09 Sep 2020 00:46:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered 'No (N)'	System	09 Sep 2020 00:46:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered 'None (1)'	System	09 Sep 2020 00:46:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:14', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered '08 Sep 2020 19:46'	System	09 Sep 2020 00:46:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 2'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:52:17', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 22:55:30

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:52:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered 'No (N)'	System	09 Sep 2020 22:55:30

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered 'Yes (Y)'	System	09 Sep 2020 22:55:30

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d' User entered '30'	System	09 Sep 2020 22:55:30

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered 'None (1)'	System	09 Sep 2020 22:55:30

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:24', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered '09 Sep 2020 17:55'	System	09 Sep 2020 22:55:30

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 3'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered 'None (1)'	System	11 Sep 2020 00:55:05

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered 'No (N)'	System	11 Sep 2020 00:55:05

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered 'No (N)'	System	11 Sep 2020 00:55:05

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered 'None (1)'	System	11 Sep 2020 00:55:05

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered '10 Sep 2020 19:55'	System	11 Sep 2020 00:55:05

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 4'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered 'None (1)'	System	12 Sep 2020 00:24:33

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered 'No (N)'	System	12 Sep 2020 00:24:33

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered 'No (N)'	System	12 Sep 2020 00:24:33

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered 'None (1)'	System	12 Sep 2020 00:24:33

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:28', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered '11 Sep 2020 19:24'	System	12 Sep 2020 00:24:33

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 5'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:54', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered 'None (1)'	System	13 Sep 2020 02:22:29

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered 'No (N)'	System	13 Sep 2020 02:22:29

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:05', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered 'No (N)'	System	13 Sep 2020 02:22:29

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered 'None (1)'	System	13 Sep 2020 02:22:29

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered '12 Sep 2020 21:22'	System	13 Sep 2020 02:22:29

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 6'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered 'None (1)'	System	13 Sep 2020 22:41:00

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered 'No (N)'	System	13 Sep 2020 22:41:00

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:43', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered 'No (N)'	System	13 Sep 2020 22:41:00

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:48', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered 'None (1)'	System	13 Sep 2020 22:41:00

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:54', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered '13 Sep 2020 17:40'	System	13 Sep 2020 22:41:00

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 7'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:05', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:18', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:22', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'No (N)'	System	08 Sep 2020 14:22:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:25', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered '08 Sep 2020 09:22'	System	08 Sep 2020 14:22:34

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:04'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:34'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:30', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'No interference with activity (1)'	System	09 Sep 2020 00:47:09

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:34', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:39', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:49', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'No (N)'	System	09 Sep 2020 00:47:09

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:47:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered '08 Sep 2020 19:47'	System	09 Sep 2020 00:47:09

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 2'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:34', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:39', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:47', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Sep 2020 22:56:18

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:56:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No (N)'	System	09 Sep 2020 22:56:18

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:56:11', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered '09 Sep 2020 17:56'	System	09 Sep 2020 22:56:18

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 3'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:13', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:20', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:23', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:26', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'No (N)'	System	11 Sep 2020 00:55:43

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:37', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered '10 Sep 2020 19:55'	System	11 Sep 2020 00:55:43

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 4'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:41', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:44', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:47', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:56', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'No (N)'	System	12 Sep 2020 00:25:05

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:25:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered '11 Sep 2020 19:25'	System	12 Sep 2020 00:25:05

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 5'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:41', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:23:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:23:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'No (N)'	System	13 Sep 2020 02:23:39

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:23:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered '12 Sep 2020 21:23'	System	13 Sep 2020 02:23:39

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 6'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:05', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:15', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:17', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:22', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'No (N)'	System	13 Sep 2020 22:41:36

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:30', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered '13 Sep 2020 17:41'	System	13 Sep 2020 22:41:36

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 7'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:42:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

US3012098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:01

US3012098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:01

US3012098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:01

US3012098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:01

US3012098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:05

US3012098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 21:12:05

US3012098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:54

US3012098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:54

US3012098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:54

US3012098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:54

US3012098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:58

US3012098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 15:48:58

US3012098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:35

US3012098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:35

US3012098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:35

US3012098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:35

US3012098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:38

US3012098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 21:34:38

US3012098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:39:28

US3012098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:39:28

US3012098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:39:28

US3012098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	13 Oct 2020 21:39:28

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '15:15'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 15:15'	System	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '98'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '111'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '67'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 21:40:02

US3012098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:25

US3012098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:25

US3012098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:42

US3012098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:42

US3012098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:00'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:42

US3012098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 16:00'	System	13 Oct 2020 21:40:42

US3012098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:59

US3012098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Oct 2020 21:40:59

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 64'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[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 (f6748508af78273b)', Time: '2020-10-14T18:08:49', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9f69e4cb-b532-462d-a168-af45ee13d9b2'	System	14 Oct 2020 23:09:15
User entered 'No (N)'	System	14 Oct 2020 23:09:15

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Have you been exposed to someone with 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 (f6748508af78273b)', Time: '2020-10-14T18:08:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9f69e4cb-b532-462d-a168-af45ee13d9b2'	System	14 Oct 2020 23:09:15
User entered 'No (N)'	System	14 Oct 2020 23:09:15

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-14T18:09:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9f69e4cb-b532-462d-a168-af45ee13d9b2'	System	14 Oct 2020 23:09:15
User entered '14 Oct 2020 18:09:07'	System	14 Oct 2020 23:09:15

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '10 Oct 2020 00:01'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '14 Oct 2020 23:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 71'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[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 (f6748508af78273b)', Time: '2020-10-17T02:45:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '3ffef26c-5588-4092-ae38-6c1d99b736d7'	System	17 Oct 2020 07:45:22
User entered 'No (N)'	System	17 Oct 2020 07:45:22

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Have you been exposed to someone with 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 (f6748508af78273b)', Time: '2020-10-17T02:45:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '3ffef26c-5588-4092-ae38-6c1d99b736d7'	System	17 Oct 2020 07:45:22
User entered 'No (N)'	System	17 Oct 2020 07:45:22

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-17T02:45:18', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '3ffef26c-5588-4092-ae38-6c1d99b736d7'	System	17 Oct 2020 07:45:22
User entered '17 Oct 2020 02:45:18'	System	17 Oct 2020 07:45:22

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '17 Oct 2020 00:01'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '21 Oct 2020 23:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 78'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[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 (f6748508af78273b)', Time: '2020-10-28T19:49:32', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0606bb89-6142-4807-9171-db2c61880860'	System	29 Oct 2020 00:49:47
User entered 'No (N)'	System	29 Oct 2020 00:49:47

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Have you been exposed to someone with 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 (f6748508af78273b)', Time: '2020-10-28T19:49:35', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0606bb89-6142-4807-9171-db2c61880860'	System	29 Oct 2020 00:49:47
User entered 'No (N)'	System	29 Oct 2020 00:49:47

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-28T19:49:41', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0606bb89-6142-4807-9171-db2c61880860'	System	29 Oct 2020 00:49:47
User entered '28 Oct 2020 19:49:41'	System	29 Oct 2020 00:49:47

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '24 Oct 2020 00:01'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '28 Oct 2020 23:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 92'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[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 (f6748508af78273b)', Time: '2020-11-10T18:00:44', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'dcf06b24-32dc-42a3-b30c-ef83706a00b0'	System	11 Nov 2020 00:01:03
User entered 'No (N)'	System	11 Nov 2020 00:01:03

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

Have you been exposed to someone with 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 (f6748508af78273b)', Time: '2020-11-10T18:00:48', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'dcf06b24-32dc-42a3-b30c-ef83706a00b0'	System	11 Nov 2020 00:01:03
User entered 'No (N)'	System	11 Nov 2020 00:01:03

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-11-10T18:00:56', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'dcf06b24-32dc-42a3-b30c-ef83706a00b0'	System	11 Nov 2020 00:01:03
User entered '10 Nov 2020 18:00:56'	System	11 Nov 2020 00:01:03

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '07 Nov 2020 00:01'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '11 Nov 2020 23:59'	System	11 Aug 2020 00:33:30

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '07 Oct 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '11 Oct 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:22:57

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:22:57

US3012098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	03 Nov 2020 20:50:16

US3012098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Nov 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:50:16

US3012098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Pamela Fidler (b) (4)	03 Nov 2020 20:50:16

US3012098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:50:16

US3012098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	03 Nov 2020 20:50:34

US3012098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 20:50:34

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 08:42:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 08:42:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 08:42:01

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 08:42:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 08:42:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 08:42:01

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 08:42:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 08:42:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 08:42:01

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 08:42:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 08:42:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 08:42:01

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 08:42:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 08:42:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 08:42:01

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 08:42:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 08:42:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 08:42:01

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 08:42:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 08:42:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 08:42:01

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:33:52

US3012098

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:13

US3012098

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:13

US3012098

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:13

US3012098

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	03 Nov 2020 14:31:13

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '09:34'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 09:34'	System	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '62.5' in	Jennifer Leyva (b) (4)	03 Nov 2020 14:31:58
DataPoint set to visible.	(b) (4) System	03 Nov 2020 14:31:13

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
User entered '166.2' lb	Jennifer Leyva (b) (4)	03 Nov 2020 14:31:58
DataPoint set to visible.	(b) (4) System	03 Nov 2020 14:31:13

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '105'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Nov 2020 14:31:58

US3012098

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:32:17

US3012098

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:32:17

US3012098

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:42:01

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:32:33

US3012098

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:42:01

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:32:33

US3012098

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:32:38

US3012098

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:32:38

US3012098

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 14:32:38

US3012098

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:42:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	03 Nov 2020 14:32:38

US3012098

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:42:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:56
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4)	01 Oct 2020 21:57:02
User entered 'No (N)'	Jennifer Leyva (b) (4)	08 Sep 2020 13:17:34

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:32:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:28
User entered 'USA-US006-2020-mRNA-1273-P301000002'	System	02 Oct 2020 12:35:23
User entered 'New'	(b) (4), (b) (6)	02 Oct 2020 12:35:23

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:32:20
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:46:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:29:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:29:44
Data point term sent to Coder	System	20 Oct 2020 14:28:21
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:07
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:01
User entered 'Colitis' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:01
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:20:24
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:25
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Unknown. Subject is currently in ICU and unable to speak or provide further information.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:44:08
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:07:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:59:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:59:57
Data point term sent to Coder	System	01 Oct 2020 21:59:31

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Abdominal pain'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:32:28
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:32:30
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:32:32
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: The onset date for the event of colitis was updated from 26 Sep 2020 to 24 Sep 2020 (2 days prior to hospital admission). Please provide any signs, symptoms or details that led to the updated onset date for this event.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:24:25
Query 'PV Query: The onset date for the event of colitis was updated from 26 Sep 2020 to 24 Sep 2020 (2 days prior to hospital admission). Please provide any signs, symptoms or details that led to the updated onset date for this event.' answered with 'Abdominal pain which was later diagnosed as Colitis began 24-Sep-2020' (Site from Safety).	Jennifer Leyva (b) (4)	05 Nov 2020 17:51:43
User opened query 'PV Query: The onset date for the event of colitis was updated from 26 Sep 2020 to 24 Sep 2020 (2 days prior to hospital admission). Please provide any signs, symptoms or details that led to the updated onset date for this event.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:18:01
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 16:00:12
User closed query 'Source states 24Sept20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 16:00:10
Query 'Source states 24Sept20. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4)	29 Oct 2020 20:22:37
User entered '24 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	29 Oct 2020 20:22:01
User opened query 'Source states 24Sept20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:32:57
User entered '26 Sep 2020'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:00
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 16:00:39
User closed query 'Source does not have an end date. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 16:00:37
Query 'Source does not have an end date. Please review and clarify. ' answered with 'source updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:22:55
User opened query 'Source does not have an end date. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:33:17
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Oct 2020 14:28:23
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:23
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Oct 2020 14:28:01
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 16:00:40
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:35
User closed query 'PV Query: Please provide the event end date of abdominal pain (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:47:05
Query 'PV Query: Please provide the event end date of abdominal pain (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:28:41
User entered '30 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Oct 2020 14:28:01
User opened query 'PV Query: Please provide the event end date of abdominal pain (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:19:31
User entered empty.	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:39
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:30
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:44:17
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:46:00
User entered empty.	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:42
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).	System	01 Oct 2020 22:01:28
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	01 Oct 2020 21:58:38
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:43
User entered '0'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38
	(b) (4)	

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:45
User entered '0'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38
	(b) (4)	

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:50
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) (6)	05 Oct 2020 12:26:17
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 'Not yet discharged. Currently hospitalized.' (Site from System).	Jennifer Leyva (b) (4)	01 Oct 2020 22:02:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	01 Oct 2020 22:01:28
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	01 Oct 2020 22:01:28
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	01 Oct 2020 22:01:28
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	01 Oct 2020 22:01:28
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	01 Oct 2020 21:58:38
User entered '0'	System	01 Oct 2020 21:58:38
	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38
	(b) (4)	

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:52
User entered '26 Sep 2020'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38
	(b) (4)	

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:18
DataPoint Un-verified.	Jennifer Leyva (b) (4)	10 Nov 2020 15:16:36
User entered '12 Oct 2020' reason for change: New Information	Jennifer Leyva (b) (4)	10 Nov 2020 15:16:36
User closed query 'PV Query: The hospital discharge date is reported as 13 Oct 2020 for event Colitis; however, the discharge date is reported as 12 Oct 2020 for the event c-diff. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:21:27
Query 'PV Query: The hospital discharge date is reported as 13 Oct 2020 for event Colitis; however, the discharge date is reported as 12 Oct 2020 for the event c-diff. Please update as applicable.' answered with 'Corrected on C-Diff CRF' (Site from Safety).	Jennifer Leyva (b) (4)	30 Oct 2020 19:12:00
User opened query 'PV Query: The hospital discharge date is reported as 13 Oct 2020 for event Colitis; however, the discharge date is reported as 12 Oct 2020 for the event c-diff. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:45:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:33:54
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:47:13
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:28:44
User entered '13 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Oct 2020 14:28:01
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:20:40
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:35
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Will provide when available. Subject is currently hospitalized.' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:44:35

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Generated On: 26 Nov 2020 08:42:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:08:04
User entered empty.	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:17
User entered 'No (N)'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:18
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:20
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:21
User entered '0'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:23
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:24
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:25
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:27
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 16:00:52
User closed query 'Source does not have a check box in section for Other Action Taken. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 16:00:51
Query 'Source does not have a check box in section for Other Action Taken. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4)	29 Oct 2020 20:23:02
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	29 Oct 2020 20:22:01
User opened query 'Source does not have a check box in section for Other Action Taken. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:30
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:34:29
User entered '1'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 16:00:56
User closed query ' SAE narrative indicates ConMed taken for this event but not indicated on CRF or on AE source page. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 16:00:54
Query ' SAE narrative indicates ConMed taken for this event but not indicated on CRF or on AE source page. Please clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:23:12
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:22:01
User opened query ' SAE narrative indicates ConMed taken for this event but not indicated on CRF or on AE source page. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:37:09
Query 'SAE narrative indicates ConMed taken for this event but not indicated on CRF. Please clarify. ' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:36:56
User opened query 'SAE narrative indicates ConMed taken for this event but not indicated on CRF. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:36:43
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 19:36:13
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:35:25
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:35:27
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:35:35
User closed query 'PV Query: Please provide the final event outcome of abdominal pain, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:47:48
Query 'PV Query: Please provide the final event outcome of abdominal pain, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:28:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jennifer Leyva (b) (4)	20 Oct 2020 14:28:01
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome of abdominal pain, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:19:51
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:40
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'To be updated when applicable.' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:44:54
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:48:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:35:36
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Does exacerbation of diastolic CHF meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:31:01
User closed query 'PV Query: Subject had acute hypoxic respiratory failure secondary to COPD and exacerbation of diastolic congestive heart failure. Please add diastolic CHF to med history.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:30:59
User closed query 'PV Query: The patient was placed on bilevel positive airway pressure due to acute hypoxic respiratory failure. Please consider reporting additional SAE Acute hypoxic respiratory failure' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:30:57
User closed query 'PV Query: Please confirm if acute hypoxic respiratory failure met SAE criteria.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:30:48
Query 'PV Query: Does exacerbation of diastolic CHF meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:47
Query 'PV Query: The patient was placed on bilevel positive airway pressure due to acute hypoxic respiratory failure. Please consider reporting additional SAE Acute hypoxic respiratory failure' answered with 'Added' (Site from Safety).	Jennifer Leyva (b) (4)	18 Nov 2020 21:21:09
Query 'PV Query: Please confirm if acute hypoxic respiratory failure met SAE criteria.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4)	18 Nov 2020 21:21:00
Query 'PV Query: Subject had acute hypoxic respiratory failure secondary to COPD and exacerbation of diastolic congestive heart failure. Please add diastolic CHF to med history.' answered with 'Added' (Site from Safety).	Jennifer Leyva (b) (4)	18 Nov 2020 21:19:11
User closed query 'PV Query: Please consider merging SAE Colitis and SAE C. difficile and reporting as one event C. difficile colitis.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:27:03

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider merging SAE Colitis and SAE C. difficile and reporting as one event C. difficile colitis.' answered with 'These are two separate events. Subject reported to hospital due to abdominal pain that was diagnosed as Colitis and while at the hospital, contracted C. Diff.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	12 Nov 2020 17:46:27
User opened query 'PV Query: Does exacerbation of diastolic CHF meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:55:38
User opened query 'PV Query: Subject had acute hypoxic respiratory failure secondary to COPD and exacerbation of diastolic congestive heart failure. Please add diastolic CHF to med history.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:55:21
User opened query 'PV Query: Please consider merging SAE Colitis and SAE C. difficile and reporting as one event C. difficile colitis.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:54:59
User opened query 'PV Query: The patient was placed on bilevel positive airway pressure due to acute hypoxic respiratory failure. Please consider reporting additional SAE Acute hypoxic respiratory failure' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:54:33
User opened query 'PV Query: Please confirm if acute hypoxic respiratory failure met SAE criteria.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:54:00
User closed query 'Per DM CLR: SAE Narrative indicates that an unknown medication was given for this AE. However, there is no corresponding ConMed record that match the information. Please reconcile and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:53:11
User closed query 'PV Query: It was reported in concomitant medication section that the subject was treated for a UTI while hospitalized. If UTI is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:25:22

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Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:25:12
User closed query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:24:58
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:24:49
Query 'PV Query: It was reported in concomitant medication section that the subject was treated for a UTI while hospitalized. If UTI is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'Treatment was pre-emptive. Test results for UTI were negative.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:53:14
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'Emailed to Safety_Moderna@iqvia on 04-NOV-2020' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:52:51
Query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' answered with 'All diagnostic testing and con-meds have been entered.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:52:35

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Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'All Con-Meds and Diagnostic procedures have been entered' (Site from Safety).	Jennifer Leyva (b) (4)	05 Nov 2020 17:52:06
User opened query 'PV Query: It was reported in concomitant medication section that the subject was treated for a UTI while hospitalized. If UTI is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:18:10
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:16:47
User opened query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:16:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:16:27
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 16:52:45

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 16:52:40
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'Hospital discharge summary sent to Moderna Safety team - 11/04/2020' (Site from Safety).	Jennifer Leyva (b) (4)	04 Nov 2020 22:13:53
Query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' answered with 'Full lab panel run - normal results. Records sent to Moderna Safety Team - 11/04/20' (Site from Safety).	Jennifer Leyva (b) (4)	04 Nov 2020 22:12:48
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 14:11:03
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4)	03 Nov 2020 22:14:52
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:44:06

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:43:28
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:42:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:35:49
Query 'Per DM CLR: SAE Narrative indicates that an unknown medication was given for this AE. However, there is no corresponding ConMed record that match the information. Please reconcile and update applicable details accordingly. Otherwise, clarify.' answered with 'CM 21 updated' (Site from DM).	Jennifer Leyva (b) (4)	26 Oct 2020 12:31:15
User opened query 'Per DM CLR: SAE Narrative indicates that an unknown medication was given for this AE. However, there is no corresponding ConMed record that match the information. Please reconcile and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 15:50:57
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:49:20
User closed query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:49:05

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Audit	User	Time (GMT)
User closed query 'PV Query: Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:48:46
User closed query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc)' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:48:33
User closed query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:48:21
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:48:11
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'Not received yet' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:30:02
Query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' answered with 'Not received yet' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:29:51
Query 'PV Query: Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' answered with 'No' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:29:41
Query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc)' answered with 'Entered. General/Entire Area.' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:29:38

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Audit	User	Time (GMT)
User entered 'PATIENT REPORTED TO ER ON 26-SEP-2020 WITH SEVERE ABDOMINAL PAIN, GENERAL/ENTIRE AREA. WAS ADMITTED AND GIVEN UNKNOWN MEDICATIONS FOR PAIN. NO DIAGNOSIS AS OF YET.' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Oct 2020 14:29:27
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Records not received yet' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:28:58
Query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' answered with 'Yes. Negative.' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:27:33
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:21:42
User opened query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:21:34
User opened query 'PV Query: Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:21:17
User opened query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc)' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:21:07
User opened query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:20:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:20:07
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:58:02
User closed query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:59
User closed query 'PV Query:Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:56
User closed query 'PV Query: Please specify location of abdominal pain (periumbilical, right upper/lower quadrant, etc).' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:53
User closed query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:50
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:57:47

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'To be sent once collected' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:45:47
Query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:45:34
Query 'PV Query:Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:45:30
Query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc).' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:45:24
Query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:45:17
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No other information is known at this time as subject is in ICU and cannot speak.' (Site from Safety).	Jennifer Leyva (b) (4)	09 Oct 2020 14:45:13
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:21:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:20:54
User opened query 'PV Query:Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:09:42
User opened query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc).' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:09:00
User opened query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:08:30
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:07:20
User entered 'Patient reported to ER on 26-SEP-2020 with severe abdominal pain. Was admitted and given unknown medications for pain. No diagnosis as of yet.'	Jennifer Leyva (b) (4)	01 Oct 2020 21:58:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 21:58:38

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:50:11
User entered 'USA-US006-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	14 Oct 2020 13:50:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:07
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Clostridia infections, PT: Clostridium difficile infection, LLT: Clostridium difficile infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:36:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:36:21
Data point term sent to Coder	System	13 Oct 2020 22:06:26
User entered 'clostricfium difficile'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:09
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:11
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:13
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:19
User entered '29 Sep 2020'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:21
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:08
DataPoint Un-verified.	Jennifer Leyva (b) (4)	05 Nov 2020 17:54:54
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	05 Nov 2020 17:54:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:23
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:10
User closed query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:27:01
Query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:55:20
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:54:54
User entered '25 Oct 2020' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:54:54
User opened query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:17:21
User closed query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:42:21
Query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per PI, will update if changes. Subject still recovering.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	30 Oct 2020 19:11:23
User opened query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:47:31
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:45:17
Query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Ongoing' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:30:15
User opened query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:24:21
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:28
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:32
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Oct 2020 22:37:12
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	13 Oct 2020 22:05:41
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:34
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:40:36
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:00
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).		13 Oct 2020 22:38:02
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 by data change (Site from System).		13 Oct 2020 22:38:02
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		13 Oct 2020 22:37:12
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).		13 Oct 2020 22:37:12
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	13 Oct 2020 22:37:12
User entered '1' reason for change: Data Entry Error Jennifer Leyva	(b) (4)	13 Oct 2020 22:37:12
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	13 Oct 2020 22:05:41
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:02
User closed query 'PV Query: The hospital admission date is reported as 26 Sep 2020 for event Abdominal Pain; however, the admission date is reported as 29 Sep 2020 for the event c-diff. Please confirm the admission date or update if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:45:42
Query 'PV Query: The hospital admission date is reported as 26 Sep 2020 for event Abdominal Pain; however, the admission date is reported as 29 Sep 2020 for the event c-diff. Please confirm the admission date or update if applicable.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:30:39
User entered '26 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:30:33
User opened query 'PV Query: The hospital admission date is reported as 26 Sep 2020 for event Abdominal Pain; however, the admission date is reported as 29 Sep 2020 for the event c-diff. Please confirm the admission date or update if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:25:00
User entered '29 Sep 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:30
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	10 Nov 2020 15:16:58
DataPoint Un-verified.	(b) (4)	
	Jennifer Leyva (b) (4)	30 Oct 2020 19:09:54
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Leyva (b) (4)	30 Oct 2020 19:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 19:43:13
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Oct 2020 22:38:02
User entered empty.	(b) (4)	
	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Oct 2020 22:38:02
User entered empty.	(b) (4)	
	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 22:38:16
User entered '5' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Oct 2020 22:38:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	13 Oct 2020 22:38:02
User entered 'UNK' (non-conformant).	System	13 Oct 2020 22:38:02
User entered empty.	Jennifer Leyva (b) (4)	13 Oct 2020 22:38:02
	(b) (4)	
	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:19
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:20
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:22
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:23
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Oct 2020 22:37:12
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:27
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Oct 2020 22:37:12
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:29
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Oct 2020 22:37:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:31
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Oct 2020 22:37:12
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Oct 2020 22:05:41
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:33
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Oct 2020 22:37:12
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:35
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:58:11
User closed query ' PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query ' PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:27:19
DataPoint Un-verified.	Jennifer Leyva (b) (4)	05 Nov 2020 17:55:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Jennifer Leyva (b) (4)	05 Nov 2020 17:54:54
User opened query ' PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:17:34
User closed query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:21:50
Query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per PI, will update when applicable.' (Site from Safety).	Jennifer Leyva (b) (4)	30 Oct 2020 19:11:38
User opened query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:48:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:37

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:44:47
Query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' answered with 'Correct as entered. Still ongoing' (Site from Safety).	Jennifer Leyva (b) (4)	20 Oct 2020 14:30:48
User opened query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:24:35
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	13 Oct 2020 22:37:12
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:40
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 22:05:41
	(b) (4)	

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:43:47
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Oct 2020 22:41:15
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Oct 2020 22:41:15
User entered 'Subject was admitted to hospital on 29-Sep-2020 due to abdominal pain, was diagnosed with C-Diff 5 days later, treated and released on 12-Oct-2020.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:41:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Oct 2020 22:05:41

US3012098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:42:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Oct 2020 22:38:02

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:02:49
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:29:40
User entered	(b) (4), (b) (6)	19 Nov 2020 16:29:32
'USA-US006-2020-mRNA-1273-P301000002'		

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:02:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:18:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:18:49
Data point term sent to Coder	System	18 Nov 2020 21:21:43
User entered 'Acute Hypoxic Respiratory Failure'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:02:53
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:02:59
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:01
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:06
User entered '29 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 19:04:41
User entered '26 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 18:51:30
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 06:30:46
Query 'Data is required. Please complete.' answered with 'UNK, start and end date not clear on discharge paperwork. Subject does not know dates either.' (Site from System).	Jennifer Leyva (b) (4)	18 Nov 2020 21:21:40
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 21:20:49
User entered empty.	Jennifer Leyva (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:07:51
User entered 'No (N)'	Jennifer Leyva (b) (4)	18 Nov 2020 21:20:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:12
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 18:51:30
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 18:51:30
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 06:34:12
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'UNK, start and end date not clear on discharge paperwork. Subject does not know dates either.' (Site from System).	Jennifer Leyva (b) (4)	18 Nov 2020 21:21:44
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:20:49
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:20:49
User entered empty.	Jennifer Leyva (b) (4)	18 Nov 2020 21:20:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:15
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:17
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Jennifer Leyva (b) (4)	24 Nov 2020 19:04:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Jennifer Leyva (b) (4)	18 Nov 2020 21:20:49
	(b) (4)	

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:18
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:26
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:28
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:29
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:29:00
User entered '29 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 20:25:48
User entered '26 Sep 2020'	Jennifer Leyva (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:11:17
User entered '12 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:36
User entered 'No (N)'	Jennifer Leyva (b) (4)	18 Nov 2020 21:20:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:38
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:40
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:41
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:12:43
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:11:24
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:11:25
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:11:37
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4)	18 Nov 2020 21:20:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:29:04
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:29:05
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:29:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:13:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:13:53
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:13:55
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:24:14
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 21:24:14
User entered 'Subject reported to ER with abdominal pain. During course of hospitalization, subject experienced acute hypoxic respiratory failure. Unknown what date this occurred or how long it lasted.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:24:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:20:49
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 21:20:49

US3012098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 21:20:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:30:19
User entered	(b) (4), (b) (6)	19 Nov 2020 16:30:15
'USA-US006-2020-mRNA-1273-P301000002'		

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:25
User coded data point as SOC: Cardiac disorders, HLT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive cardiac failure aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 22:21:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 22:21:49
Data point term sent to Coder	System	18 Nov 2020 21:23:47
User entered 'Exacerbation of Diastolic CHF'	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:28
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:30
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:33
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:00
User entered '29 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 19:05:21
User entered '26 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 18:51:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 06:36:06
Query 'Data is required. Please complete.' answered with 'UNK, start and end date not clear on discharge paperwork. Subject does not know dates either.' (Site from System).	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:53
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 21:22:46
User entered empty.	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:39
User entered 'No (N)'	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:05
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 18:52:20
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	(b) (4)	
	System	24 Nov 2020 18:51:59
User entered '13 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 18:51:59
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 06:37:16
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'UNK, start and end date not clear on discharge paperwork. Subject does not know dates either.' (Site from System).	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:56
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:22:46
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:22:46
User entered empty.	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:06
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:08
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 19:05:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:11
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:13
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:14
User entered 'I'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:29:14
User entered '29 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 20:26:13
User entered '26 Sep 2020'	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:26
User entered '12 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:29
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:30
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:32
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:33
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:34
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:46
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:47
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:12:49
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:29:17
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:29:19
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:29:22
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Leyva (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:24:56
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 21:24:56
User entered 'SUBJECT REPORTED TO ER WITH ABDOMINAL PAIN. DURING COURSE OF HOSPITALIZATION, SUBJECT EXPERIENCED AN EXACERBATION OF CONGESTIVE HEART FAILURE. UNKNOWN WHAT DATE THIS OCCURRED OR HOW LONG IT LASTED.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:24:56
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:22:46
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 21:22:46

US3012098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 21:22:46

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User closed query 'Medication of furosemide in source but not entered in EDC. Please consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 16:02:46
Query 'Medication of furosemide in source but not entered in EDC. Please consider adding to EDC. ' answered with 'Entered 28-Oct (CM #25)' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:15:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:08
User opened query 'Medication of furosemide in source but not entered in EDC. Please consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:52:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:30:23

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:33:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:33:18
Data point term sent to Coder	System	11 Aug 2020 01:32:01
User entered 'albuterol'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:31:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'emphysema'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '90'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:33:39
Query 'Per DM CLR: Please review the Frequency as Jennifer Leyva this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'Correct as entered. Med can be used As Needed' (Site from DM).	(b) (4)	21 Sep 2020 18:19:23
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 12:43:58
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:23:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:31:20
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:31:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 01:31:16
User entered 'Un UNK 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 01:31:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 01:31:07
User entered 'uj UNK 2019' (non-conformant).	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med ABILIFY was added on 10 AUG 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:34:12
Query 'Per DM CLR: Con Med ABILIFY was added on 10 AUG 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' answered with 'Updated. Date of Visit entered inadvertently.' (Site from DM).	Jennifer Leyva (b) (4)	21 Sep 2020 18:20:27
User opened query 'Per DM CLR: Con Med ABILIFY was added on 10 AUG 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 11:14:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 01:33:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 01:33:18
Data point term sent to Coder	System	11 Aug 2020 01:33:01
User entered 'abilify'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'depression'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000' reason for change:	Jennifer Leyva (b) (4)	21 Sep 2020 18:20:13
Data Entry Error	(b) (4)	
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:35:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:35:20
Data point term sent to Coder	System	11 Aug 2020 01:34:02
User entered 'atorvastatin'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:28:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:33:07
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:33:03
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:33:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:17:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:17:10
Data point term sent to Coder	System	11 Aug 2020 01:34:02
User entered 'clonidine'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety, hypertension'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:06:00
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 22:56:54
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 12:46:40
User entered '100'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)' reason for change: Data Entry	Jennifer Leyva (b) (4)	30 Sep 2020 22:56:37
Error	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:28:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:33:57
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:33:54
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: DEXLANSOPRAZOLE, PRODUCTSYNONYM: DEXILANT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:35:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:35:20
Data point term sent to Coder	System	11 Aug 2020 01:35:02
User entered 'dexilant'	(b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:34:48
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Reported as entered by subject.' (Site from DM).	Jennifer Leyva (b) (4)	21 Sep 2020 18:21:20
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 12:47:36
User entered 'diverticulitis'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:28:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:34:49
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:34:45
User entered 'un UNK 2017'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DOXEPIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 10:50:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 10:50:13
Data point term sent to Coder	System	11 Aug 2020 01:36:03
User entered 'doxepin'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:28:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:35:27
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:35:22
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 01:37:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 01:37:23
Data point term sent to Coder	System	11 Aug 2020 01:37:03
User entered 'fish oil'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'nutritional supplement'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:28:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:36:22
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:36:18
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:36:18

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:22:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:22:49
Data point term sent to Coder	System	21 Sep 2020 18:22:18
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:21:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:39:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:39:16
Data point term sent to Coder	System	11 Aug 2020 01:38:04
User entered 'flonase'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = Yes. However, please review if the response should be updated to 'No' instead as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:35:20
Query 'Per DM CLR: Prophylaxis = Yes. However, please review if the response should be updated to 'No' instead as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate.'	Jennifer Leyva (b) (4)	21 Sep 2020 18:21:50
answered with 'Updated' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	21 Sep 2020 18:21:36
User opened query 'Per DM CLR: Prophylaxis = Yes. However, please review if the response should be updated to 'No' instead as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:30:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal allergies'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:43:30
Query 'Per DM CLR: Please review the Frequency as Jennifer Leyva this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'Correct as entered.' (Site from DM).	(b) (4)	21 Sep 2020 18:22:00
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:27:00
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (i.e. Nasal).' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:43:35
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (i.e. Nasal).' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4)	21 Sep 2020 18:21:53
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	21 Sep 2020 18:21:46
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (i.e. Nasal).' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:27:35
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:28:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:37:39
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:37:35
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:40:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:40:17
Data point term sent to Coder	System	11 Aug 2020 01:39:04
User entered 'glucosamine chondroitin'	(b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'nutritional supplement'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:28:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:38:33
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:38:27
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:41:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:41:18
Data point term sent to Coder	System	11 Aug 2020 01:40:05
User entered 'hydrocodone/apap'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:01:58
User opened query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 08:00:29
User entered 'osteoarthritis'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10/325'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:07:05
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 22:58:12
User entered 'UN UNK 2010' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	30 Sep 2020 22:58:07
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 08:01:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:29:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 01:39:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:39:37
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: XANTHINES, PRODUCT: DIPROPHYLLINE, PRODUCTSYNONYM: ASTELIN [DIPROPHYLLINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
Data point term sent to Coder	System	11 Aug 2020 01:41:06
User entered 'astelin'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'emphysema'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '137'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:07:23
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'Correct as entered. Med can be used on as needed basis' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 22:58:31
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 08:02:55
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:08:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 22:58:48
User entered 'UN UNK 2019' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	30 Sep 2020 22:58:43
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 08:03:32
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:29:21
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 01:40:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:40:32
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 01:43:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 01:43:20
Data point term sent to Coder	System	11 Aug 2020 01:42:07
User entered 'hydroxyzine'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'insomnia'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:29:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:41:38
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:41:34
User entered 'un UNK 2018'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:16:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:16:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:44:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:44:21
Data point term sent to Coder	System	11 Aug 2020 01:43:07
User entered 'IRON' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:43:01
User entered 'jiron'	(b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = No. However, kindly review and confirm if the response should be updated to 'Yes' instead since this medication is used as a prophylaxis/supplement.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:34:36
Query 'Per DM CLR: Prophylaxis = No. However, kindly review and confirm if the response should be updated to 'Yes' instead since this medication is used as a prophylaxis/supplement.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 22:59:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 22:59:04
User opened query 'Per DM CLR: Prophylaxis = No. However, kindly review and confirm if the response should be updated to 'Yes' instead since this medication is used as a prophylaxis/supplement.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:23:49
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'nutritional supplement'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:09:18
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UNK. Confirmed with pt, dosage not known.' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 22:59:31
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:24:03
User entered '2'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:29:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:42:36
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:42:31
User entered 'un UNK 2017'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:45:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:45:22
Data point term sent to Coder	System	11 Aug 2020 01:44:09
User entered 'lamotrigine'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:41:42
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MEDICAL HISTORY UPDATED' (Site from DM).	Lamar Box (b) (4)	03 Oct 2020 01:23:03
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 12:45:00
User entered 'bipolar disorder'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:29:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:44:08
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:44:04
User entered 'un UNK 2018'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:44:04

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 01:47:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 01:47:24
Data point term sent to Coder	System	11 Aug 2020 01:46:10
User entered 'levothyroxine'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypothyroidism'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

Dose unit

Audit	User	Time (GMT)
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. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:09:55
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. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 23:00:28
User entered 'ug (ug)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	30 Sep 2020 23:00:25
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. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 12:45:47
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:30:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:45:21
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:45:17
User entered 'un UNK 2018'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:45:17

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:48:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:48:26
Data point term sent to Coder	System	11 Aug 2020 01:47:11
User entered 'metoprolol'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:10:02
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 23:01:38
User entered '25' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	30 Sep 2020 23:01:34
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 08:04:31
User entered '20'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:10:31
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	30 Sep 2020 23:01:41
User entered 'UN UNK 2019' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	30 Sep 2020 23:01:34
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 08:05:45
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:30:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 01:46:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:46:11
User entered 'un UNK 2018'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:46:11

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 01:26:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 01:26:54
Data point term sent to Coder Coding entries removed.	System Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:26:10 03 Oct 2020 01:26:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:20:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:20:08
Data point term sent to Coder User entered 'montelukast'	System (b) (4), (b) (6) (b) (4)	11 Aug 2020 01:47:13 11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:40:53
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'DATA CORRECTED' (Site from DM).	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:26:13
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:26:05
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 08:07:27
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:30:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:47:13
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:47:09
User entered 'un UNK 2017'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:47:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:06:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:06:14
Data point term sent to Coder	System	11 Aug 2020 01:48:13
User entered 'topiramate'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'fibromyalgia'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:30:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:48:13
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:48:09
User entered 'un UNK 2017'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:50:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:50:16
Data point term sent to Coder	System	11 Aug 2020 01:49:14
User entered 'trintellix'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'depression'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:30:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 01:48:59
answered with 'this is current medication.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:48:56
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 01:48:56

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:21:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:21:24
Data point term sent to Coder	System	13 Oct 2020 21:46:01
User entered 'vancomycin'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:38
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:43
User entered 'C-Diff'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:46
User entered '125'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:48
User entered 'mg (mg)'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:50
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:51
User entered 'four times daily (QID)'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:53
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:54
User entered 'Oral (ORAL)'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:56
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:45:58
User entered '29 Sep 2020'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:46:00
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Leyva (b) (4)	24 Nov 2020 21:49:00
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	24 Nov 2020 21:49:00
	(b) (4)	
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:39:26
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'Correct as entered. CM is ongoing for prevention' (Site from DM).	Jennifer Leyva (b) (4)	20 Nov 2020 13:50:02
	(b) (4)	
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:12:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:46:02
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Leyva (b) (4)	24 Nov 2020 21:49:00
	(b) (4)	
User entered '22 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 21:49:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:46:05
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:46:08
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:45:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Oct 2020 21:45:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 21:45:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 21:45:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:46:52
Query 'Please add medications taken for SAEs to source ConMed logs. ' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:45:15
User opened query 'Please add medications taken for SAEs to source ConMed logs. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:45:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 20:48:39
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 Oct 2020 20:48:39
Data point term sent to Coder	System	26 Oct 2020 12:31:26
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	26 Oct 2020 12:31:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:59:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:59:19
Data point term sent to Coder	System	13 Oct 2020 21:47:02
User entered 'dicyclomine'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:46:54
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 16:02:14
User closed query 'Source still indicates infection prophylaxis. Please ensure source and eCRF match. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 16:02:13
Query 'Source still indicates infection prophylaxis. Please ensure source and eCRF match. ' answered with 'source corrected' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:18:38
User opened query 'Source still indicates infection prophylaxis. Please ensure source and eCRF match. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:46:50
User entered 'Colitis (AE #1)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	26 Oct 2020 12:31:09
User entered 'infection prophylaxis'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:00
User entered '20'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:02
User entered 'mg (mg)'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:04
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:05
User entered 'four times daily (QID)'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:06
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:09
User entered 'Oral (ORAL)'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:10
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:12
User entered '29 Sep 2020'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:13
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Leyva (b) (4)	24 Nov 2020 21:49:19
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4)	24 Nov 2020 21:49:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:15
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Leyva (b) (4)	24 Nov 2020 21:49:19
	(b) (4)	
User entered '12 Oct 2020' reason for change: New Information	Jennifer Leyva (b) (4)	24 Nov 2020 21:49:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:17
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:18
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:46:09
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:26
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: ONDASETRON [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:33:28
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 Oct 2020 05:33:28
Data point term sent to Coder	System	13 Oct 2020 21:48:04
User entered 'ondasetron'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:29
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:38:25
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Medication related from hospitalization' (Site from DM).	Pamela Fidler (b) (4)	03 Nov 2020 20:49:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:09:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:32
User entered 'nausea'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:34
User entered '4'	Katherine Davis (b) (4)	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:36
User entered 'mg (mg)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:37
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:38
User entered 'other (OTHER)'	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:41
User entered 'Q6H/PRN'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:43
User entered 'Oral (ORAL)'	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:44
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:47
User entered '28 Sep 2020'	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:48
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:50
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:52
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:54
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:47:19
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:47:19

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:47:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: ESTERS OF AMINOBENZOIC ACID, PRODUCT: BENZOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:51:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:51:26
Data point term sent to Coder	System	13 Oct 2020 21:49:05
User entered 'benzocaine 20%'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:01
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:38:36
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Due to Hospitalization' (Site from DM).	Pamela Fidler (b) (4)	03 Nov 2020 20:49:51
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:10:18
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:03
User entered 'cracked tongue , fever blister'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:06
User entered '1'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:07
User entered 'Other (OTHER)'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:08
User entered 'application'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:12
User entered 'as needed (PRN)'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:15
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:17
User entered 'Topical (TOPICAL)'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:18
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:20
User entered '10 Oct 2020'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:22
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:24
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:26
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:28
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:48:59
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:35
User coded data point as ATC: DERMATOLOGICALS, ATC: EMOLLIENTS AND PROTECTIVES, ATC: EMOLLIENTS AND PROTECTIVES, ATC: SILICONE PRODUCTS, PRODUCT: DIMETICONE, PRODUCTSYNONYM: DIMETHICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:00:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:00:21
Data point term sent to Coder	System	13 Oct 2020 21:54:09
User entered 'dimethicone 1.5%'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:48:37
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:38:46
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Due to hospitalization' (Site from DM).	Pamela Fidler (b) (4)	03 Nov 2020 20:50:03
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:10:38
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:27
User entered 'body aches/weakness'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:33
User entered '1'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:35
User entered 'Other (OTHER)'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:36
User entered 'application'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:38
User entered 'as needed (PRN)'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:40
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:41
User entered 'Topical (TOPICAL)'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:43
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:44
User entered '10 Oct 2020'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:46
User entered '0'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:47
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:48
User entered empty.	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:49:50
User entered 'No (N)'	Katherine Davis (b) (4)	13 Oct 2020 21:54:03
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:54:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:54:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:54:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:15:56
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 Oct 2020 21:15:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:33
Data point term sent to Coder	System	28 Oct 2020 22:07:42
User entered 'Furosemide'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:40
User entered 'Diuretic, from hospitalization'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:43
User entered '40'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:50
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:52
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:56
User entered 'three times daily (TID)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:58
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:59
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:01
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:02
User entered '29 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:04
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:05
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:07
User entered '01 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:09
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 20:49:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	20 Nov 2020 20:49:18
Data point term sent to Coder	System	03 Nov 2020 20:54:07
User entered 'Metronidazole'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:27
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:31
User entered 'UTI treatment part of hospitalization'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:33
User entered '500'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:35
User entered 'mg (mg)'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:43
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:41
User entered 'other (OTHER)'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:45
User entered 'QgH'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:46
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:53
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:48
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:52
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:55
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:56
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:16:58
User entered '01 Oct 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:00
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:53:15

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:21
Data point term sent to Coder	System	03 Nov 2020 20:55:07
User entered 'Morphine Sulfate'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:16
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:18
User entered 'Pain in Abdomen part of hospitalization'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:25
User entered '4'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:31
User entered 'mg (mg)'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:33
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:34
User entered 'as needed (PRN)'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:36
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:38
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:52
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:56
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:17:58
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:18:00
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:18:02
User entered '13 Oct 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:18:15
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:00
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 09:03:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 09:03:25
Data point term sent to Coder	System	03 Nov 2020 20:56:10
User entered 'Metronidazole'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:59
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:55
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:44
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:02
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:46
User entered 'UTI treatment pre-emptive part of hospitalization'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:30:48
User entered '100'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:14
User entered 'mL (mL)'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:15
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:16
User entered 'other (OTHER)'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:19
User closed query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. four times daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:13:12
Query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. four times daily). Kindly update as appropriate, else clarify.' answered with 'Correct as entered this is how it was prescribed by the physician' (Site from DM).	Pamela Fidler (b) (4)	11 Nov 2020 17:37:51
User opened query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. four times daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:25:32
User entered 'Q6H'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:23
User entered 'Intravenous (INTRAVENOUS)'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:25
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:26
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:28
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:31
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:32
User entered '01 Oct 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:33
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PANTOPRAZOLE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 20:57:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 20:57:33
Data point term sent to Coder	System	03 Nov 2020 20:57:11
User entered 'Pantoprazole Sodium'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:42
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:45
User entered 'GERD during hospitalization'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:46
User entered '40'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:48
User entered 'mg (mg)'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:50
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:52
User entered 'once daily (QD)'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:53
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:56
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:58
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:31:59
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:01
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:03
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:04
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 20:30:34
User entered '13 Oct 2020'	(b) (4)	
	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:06
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PANTOPRAZOLE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:57:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:57:33
Data point term sent to Coder	System	03 Nov 2020 20:57:11
User entered 'Pantoprazole Sodium'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:20
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:22
User entered 'GERD during hospitalization'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:23
User entered '40'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:25
User entered 'mg (mg)'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:27
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:28
User entered 'once daily (QD)'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:30
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:31
User entered 'Intravenous (INTRAVENOUS)'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:32
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:34
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:35
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:37
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:38
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 20:30:12
User entered '13 Oct 2020'	(b) (4)	
	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:40
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 20:57:05

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:24:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:24:24
Data point term sent to Coder	System	03 Nov 2020 20:58:12
User entered 'Polyethylene Glycol'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:21
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:23
User entered 'Pain in Abdomen dx colitis'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:25
User entered '17'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:27
User entered 'g (g)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:28
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:30
User entered 'as needed (PRN)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:31
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:33
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:35
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:36
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:38
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:39
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:45
DataPoint Un-verified.	Jennifer Leyva (b) (4)	24 Nov 2020 20:31:03
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 20:31:03
DataPoint Verified.	Jennifer Leyva (b) (4)	24 Nov 2020 20:20:41
User entered '13 Oct 2020'	(b) (4), (b) (6)	24 Nov 2020 20:20:41
	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:42
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:58:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: TRAMADOL HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:00:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:00:26
Data point term sent to Coder	System	03 Nov 2020 20:59:14
User entered 'Tramadol HCL'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:51
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:52
User entered 'Pain in abdomen dx Colitis during hospitalization'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:55
User entered '100'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:56
User entered 'mg (mg)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:58
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:20:59
User entered 'twice daily (BID)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:01
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:04
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:05
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:07
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:08
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:50
DataPoint Un-verified.	Jennifer Leyva (b) (4)	24 Nov 2020 20:31:12
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 20:31:12
DataPoint Verified.	Jennifer Leyva (b) (4)	24 Nov 2020 20:31:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:10
	(b) (4), (b) (6)	
User entered '13 Oct 2020'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54
	(b) (4)	
	(b) (4)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:15
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 20:58:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: UMECLIDINIUM;VILANTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:18:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:18:27
Data point term sent to Coder	System	03 Nov 2020 21:03:20
User entered 'Vilanterol/Umeclidinium'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:21:51
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:20
User entered 'COPD- During hospitalization'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:22
User entered '1'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:24
User entered 'puff (PUFF)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:25
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:27
User entered 'as needed (PRN)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:32
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:33
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:35
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:36
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:38
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:39
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:54
DataPoint Un-verified.	Jennifer Leyva (b) (4)	24 Nov 2020 20:31:21
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 20:31:21
DataPoint Verified.	Jennifer Leyva (b) (4)	24 Nov 2020 20:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:41
	(b) (4), (b) (6)	
User entered '13 Oct 2020'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:22:44
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:03:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:16:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:16:29
Data point term sent to Coder	System	03 Nov 2020 21:04:21
User entered 'Vortioxetine'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:04
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:05
User entered 'Depression - During hospitalization'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:07
User entered '20'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:08
User entered 'mg (mg)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:09
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:11
User entered 'once daily (QD)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:12
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:14
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:15
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:20
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:21
User entered '0'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:23
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:24
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	24 Nov 2020 20:31:31
User entered '13 Oct 2020'	(b) (4)	
	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:27
User entered 'No (N)'	Pamela Fidler (b) (4)	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 21:03:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:08
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:43:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:43:00
Data point term sent to Coder	System	24 Nov 2020 21:41:43
User entered 'Influenza Vaccine'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:06
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:03
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Influenza Prevention'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	(b) (4) Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	(b) (4) Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	(b) (4) Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	(b) (4) Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	(b) (4) Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	(b) (4) Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	(b) (4) Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	(b) (4) Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	(b) (4) Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	(b) (4) Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) [REDACTED] [REDACTED]	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) [REDACTED] [REDACTED]	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) [REDACTED] [REDACTED]	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:04
Data point term sent to Coder	System	24 Nov 2020 21:47:51
User entered 'Shingles Vaccine'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Shingles Prevention'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '05'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON, PRODUCTSYNONYM: MYRBETRIQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:49:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:49:05
Data point term sent to Coder	System	24 Nov 2020 21:47:52
User entered 'Myrbetriq'	Jennifer Leyva (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Overactive Bladder'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
User entered '03 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:47:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:15:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:15:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:29
Data point term sent to Coder	System	24 Nov 2020 21:47:52
User entered 'Dicyclomine'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:31
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:32
User entered 'Colitis prevention'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:34
User entered '20'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:37
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:39
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:41
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:42
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:43
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:45
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:48
User entered '13 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:49
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:51
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:53
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:54
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 08:42:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:47:45

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:42:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:03
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4)	28 Oct 2020 22:06:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	11 Aug 2020 01:30:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 01:29:54

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:42:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered '29 Sep 2020'	Jennifer Leyva (b) (4)	28 Oct 2020 22:09:49
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:42:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered 'Chest CT for pulmonary embolus, negative'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:09:49

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	28 Oct 2020 22:09:49
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:42:01

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered empty.	Jennifer Leyva (b) (4)	28 Oct 2020 22:09:49
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:42:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered '14 Oct 2020'	Jennifer Leyva (b) (4)	28 Oct 2020 22:10:18
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:42:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered 'SARS-CoV-2 test (nasal, negative)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:10:18

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	28 Oct 2020 22:10:18
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:42:01

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:10:18

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:42:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:34:32
User entered '29 Sep 2020'	Pamela Fidler (b) (4)	03 Nov 2020 21:04:45

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:42:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:34:33
User entered 'GI Panel- Bacteria PCR - Negative'	Pamela Fidler (b) (4)	03 Nov 2020 21:04:45

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:34:35
User entered 'Diagnostic (DIAGNOSTIC)'	Pamela Fidler (b) (4)	03 Nov 2020 21:04:45

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:42:01

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:34:36
User entered empty.	Pamela Fidler (b) (4)	03 Nov 2020 21:04:45

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 08:42:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered '30 Sep 2020'	Jennifer Leyva (b) (4)	24 Nov 2020 21:37:58
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 08:42:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'CHEST CT FOR PULMONARY EMBOLUS, NEGATIVE'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:37:58

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:37:58

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 08:42:01

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:37:58

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 08:42:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered '29 Sep 2020'	Jennifer Leyva (b) (4)	24 Nov 2020 21:39:25
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 08:42:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'CT Scan - Abdomen/Pelvis for diagnosis, Normal'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:25

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	24 Nov 2020 21:39:25
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 08:42:01

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:25

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 08:42:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered '30 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:46

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 08:42:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Transthoracic Echocardiograph'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:46

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:46

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 08:42:01

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered empty.	Jennifer Leyva (b) (4)	24 Nov 2020 21:39:46
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 08:42:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered '29 Sep 2020'	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:02
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 08:42:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Electrocardiogram'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:02

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 08:42:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:02
	(b) (4)	

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 08:42:01

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered empty.	Jennifer Leyva (b) (4)	24 Nov 2020 21:40:02
	(b) (4)	

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '02/Oct/2020 12:35'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '12/Oct/2020 15:58'	System	12 Oct 2020 15:58:20

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:51:48
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 15:58:20

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '14/Oct/2020 13:51'	System	14 Oct 2020 13:51:59

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:58:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 13:51:59

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '21/Oct/2020 12:35'	System	21 Oct 2020 16:35:42

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:58:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 16:35:42

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:50:56
User entered '30/Oct/2020 09:58'	System	30 Oct 2020 13:58:29

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:22:06
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:50:58
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 13:58:29

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

(b)

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:53:20
User entered '02/Nov/2020 15:22'	System	02 Nov 2020 15:22:19

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:53:22
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 14:12:07
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 15:22:19

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:52:59
User entered '04/Nov/2020 09:12'	System	04 Nov 2020 14:12:15

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:53:01
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 14:12:15

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:53:06
User entered '06/Nov/2020 12:51'	System	06 Nov 2020 17:51:29

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:53:08
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 17:51:29

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:48:36
User entered '11/Nov/2020 16:58'	System	11 Nov 2020 16:58:44

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:31:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:48:36
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 16:58:44

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:40:31
User entered '19/Nov/2020 11:31'	System	19 Nov 2020 16:31:32

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:40:31
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 16:31:32

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	System	02 Oct 2020 12:35:23

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 08:42:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:40:31
User entered '19/Nov/2020 12:47'	System	19 Nov 2020 17:47:54

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 08:42:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:40:31
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 17:47:54