

US3442113 (Prod: Benchmark Research - Fort Worth)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:43:21

All time stamps listed in this document are displayed in GMT

US3442113

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:59:19

Generated On: 09 Jun 2021 17:43:21

[Participant ID](#)

US3442113

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

US3442113

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SCRN

US3442113

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input type="radio"/> Male <input checked="" 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

US3442113

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3442113

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Were any significant conditions reported?

Yes ☒

No ☐

US3442113

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	SEASONAL ALLERGIES
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)	_____

US3442113

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	DIPLOPIA
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)	_____

US3442113

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442113

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442113

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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)	_____

US3442113

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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)	_____

US3442113

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3442113

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	HAMMERTOE: RIGHT FOOT 2ND AND 3RD TOES
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3442113

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	NECK INJURY C6 C7
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3442113

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	BENIGN NASAL POLYPS
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3442113

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	HAMMERTOES SURGERY: RIGHT FOOT 2ND AND 3RD TOE
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3442113

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	C6,C7 FUSION
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3442113

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	INSOMNIA
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)	_____

US3442113

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	GENERAL MYALGIAS
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)	

US3442113

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	GRAVES DISEASE
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442113

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	GRAVES OPTHALMOPATHY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3442113

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	NASAL POLYP SURGERY
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3442113

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Condition	NASAL POLYP SURGERY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3442113

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:28 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:28
Height (<i>xxx.x</i>)	68.5 in
Weight (<i>xxx.x</i>)	192 lb
BMI (<i>xxx.x</i>)	28.82903 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)	

US3442113

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3442113

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

DAILY ERRANDS IN THE
COMMUNITY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

33 of 2861

US3442113

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	VISIT1

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 188306

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 ☒

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Height	ND - Not Done
Weight	ND - Not Done

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

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)	1 SEP 2020
Time of assessment (00:00-23:59)	13:28 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:28
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 15:06
Temperature (xxx.x)	96.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3442113

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

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.

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 14:36 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 14:36

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

US3442113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	14:05 (24 HR)
Collection date and time (derived)	1 SEP 2020 14:05

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:09	1 SEP 2020 14:09
Nasopharyngeal Swab 2	No		

US3442113

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

01 SEP 2020 15:14

PC Open Date & Time

01 SEP 2020 14:56

PC Close Date & Time

01 SEP 2020 17:26

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

01 SEP 2020 18:21

PC Close Date & Time

02 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please record your TEMPERATURE in °F	98.3 °F
---	---------

Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

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

PC Time Stamp	02 SEP 2020 17:37
---------------	-------------------

PC Open Date & Time	02 SEP 2020 12:00
---------------------	-------------------

PC Close Date & Time	03 SEP 2020 11:59
----------------------	-------------------

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	03 SEP 2020 14:37
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 SEP 2020 20:03

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

97.1 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 SEP 2020 20:00

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	07 SEP 2020 11:25
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

08 SEP 2020 17:37

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

01 SEP 2020 15:15

PC Open Date & Time

01 SEP 2020 14:56

PC Close Date & Time

01 SEP 2020 17:26

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

02 SEP 2020 10:05

PC Open Date & Time

01 SEP 2020 18:21

PC Close Date & Time

02 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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)

8

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

02 SEP 2020 17:41

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

6

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)**

5

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

03 SEP 2020 14:41

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

04 SEP 2020 20:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

05 SEP 2020 19:57

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

07 SEP 2020 11:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 14:56

PC Close Date & Time

01 SEP 2020 17:26

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 10:01
PC Open Date & Time	01 SEP 2020 18:21
PC Close Date & Time	02 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

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 ☒

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 17:42
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

		Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 14:39	
PC Open Date & Time	03 SEP 2020 12:00	
PC Close Date & Time	04 SEP 2020 11:59	

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

71 of 2861

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:06
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

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 ☒

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:59
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

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 ☒

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 11:27
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

77 of 2861

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

08 SEP 2020 17:39

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:17

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 SEP 2020 20:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 8

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 08 SEP 2020 17:39

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 17:39
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 SEP 2020 18:17
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 20:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3442113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

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)	29 SEP 2020
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:59
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 12:10
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3442113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 11:39 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 11:39

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

US3442113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

11:05 (24 HR)

Collection date and time (derived)

29 SEP 2020 11:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:10	29 SEP 2020 11:10
Nasopharyngeal Swab 2	No		

US3442113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:11

PC Open Date & Time

29 SEP 2020 11:59

PC Close Date & Time

29 SEP 2020 14:29

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.2 °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	29 SEP 2020 20:08
PC Open Date & Time	29 SEP 2020 15:24
PC Close Date & Time	30 SEP 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

99.1 °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

30 SEP 2020 19:28

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

97.2 °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

01 OCT 2020 19:34

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

97.2 °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

02 OCT 2020 19:04

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

97.2 °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

03 OCT 2020 18:44

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

04 OCT 2020 20:52

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

05 OCT 2020 19:32

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

29 SEP 2020 12:12

PC Open Date & Time

29 SEP 2020 11:59

PC Close Date & Time

29 SEP 2020 14:29

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

6

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

29 SEP 2020 20:13

PC Open Date & Time

29 SEP 2020 15:24

PC Close Date & Time

30 SEP 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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)

105

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

30 SEP 2020 19:30

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

11

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)**

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 19:39

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

6

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

02 OCT 2020 19:04

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

03 OCT 2020 18:45

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

04 OCT 2020 20:54

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

05 OCT 2020 19:33

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 12:12
PC Open Date & Time	29 SEP 2020 11:59
PC Close Date & Time	29 SEP 2020 14:29

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 20:14
PC Open Date & Time	29 SEP 2020 15:24
PC Close Date & Time	30 SEP 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

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 ☒

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:32
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

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 ☒

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 19:40
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

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 ☒

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 19:05
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

126 of 2861

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 18:45
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

128 of 2861

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:54
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

130 of 2861

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:34
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3442113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

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.

US3442113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

12:16 (24 HR)

Collection date and time (derived)

26 OCT 2020 12:16

US3442113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:22

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 12:42:11
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

08 NOV 2020 07:14:31

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 22:23:34
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 21:25:47
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 17:37:48
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 09:50:48
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 09:40:48

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 16:14:53

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 07:11:10

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 08:27:33
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 06:05:00
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 16:00:52

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 08:45:53

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 08:07:47

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 19:44:24
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 06:53:49

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 10:42:49

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 23:59:29
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 12:00:56

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 07:14:48
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 MAR 2021 08:25:33
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 07:04:09

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 06:15:46
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 05:12:08

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 16:13:44

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 19:15:07

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 16:41:35

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 <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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	27 DEC 2021 23:59
---	-------------------

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission	
Patient Cloud Open Date & Time	19 MAY 2022 00:01
Patient Cloud Close Date & Time	23 MAY 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 <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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	11 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	15 AUG 2022 23:59
---	-------------------

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	27 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	31 OCT 2022 23:59
---	-------------------

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3442113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:43:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 23:59:58

US3442113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:59:21

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:37:15

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:37:15

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:37:15

Generated On: 09 Jun 2021 17:43:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:37:15

Generated On: 09 Jun 2021 17:43:21

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.

US3442113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:37:15

Generated On: 09 Jun 2021 17:43:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

15 MAR 2021 14:00

US3442113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:37:15

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:46:29

Generated On: 09 Jun 2021 17:43:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442113

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:46:29

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442113

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3442113

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:43:21

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"/>

US3442113

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:43:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3442113

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:59:20

Generated On: 09 Jun 2021 17:43:21

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

Visit date (dd MMM yyyy)	7 JAN 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3442113

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:37:15

Generated On: 09 Jun 2021 17:43:21

Date of updated informed consent (dd MMM yyyy) 7 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 7 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3442113

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:59:20

Generated On: 09 Jun 2021 17:43:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00-23:59)	12:26 (24 HR)
Collection date and time (derived)	7 JAN 2021 12:26

US3442113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:59:20

Generated On: 09 Jun 2021 17:43:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	12:22
Collection Date and Time (derived)	7 JAN 2021 12:22

US3442113

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:59:20

Generated On: 09 Jun 2021 17:43:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

AEID	USA-US017-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE APPENDICITIS
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)	2 SEP 2020
Start time (00:00-23:59)	21:00 (24 HR)
AE start date and time (derived)	2 SEP 2020 21:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 SEP 2020
End time (00:00-23:59)	10:51 (24 HR)
AE End Date and Time (derived)	04 SEP 2020 10:51
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)	3 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	4 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2861

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

SUBJECT REPORTED
APPENDICITIS BEGINNING ON
02SEP2020. SUBJECT CLAIMS
ABDOMINAL PAIN. SUBJECT
WENT TO ER ON 03SEP2020
@ 12:58PM AND HAD AN
EMERGENCY APPENDECTOMY.
RELEASED FROM HOSPITAL ON
04SEP2020 @10:51AM

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

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

AEID	USA-US017-2020-MRNA-1273-P30 1000001
Adverse event	LOCALIZED PERITONITIS
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)	02 SEP 2020
Start time (00:00-23:59)	21:00 (24 HR)
AE start date and time (derived)	02 SEP 2020 21:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 SEP 2020
End time (00:00-23:59)	10:51 (24 HR)
AE End Date and Time (derived)	03 SEP 2020 10:51
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)	03 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	04 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2861

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

SUBJECT REPORTED
APPENDICITIS BEGINNING ON
02SEP2020. SUBJECT CLAIMS
ABDOMINAL PAIN. SUBJECT
WENT TO ER ON 03SEP2020
@ 12:58PM AND HAD AN
EMERGENCY APPENDECTOMY.
RELEASED FROM HOSPITAL ON
04SEP2020 @10:51AM

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

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 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)	09 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2861

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Mar 2021 21:37:15

Generated On: 09 Jun 2021 17:43:21

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

Yes ☒

No ☐

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication RAMIPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication SELENIUM

Prophylaxis Yes ☐
No ☒

Indication DIPLOPIA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

364 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication SINGULAIR

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

366 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication SYMBICORT

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 160/4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.04

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONE TAB QHS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONE TAB QHS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication CETRIZINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

374 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONE TAB QHS

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

PRODUCTION RELEASE (v12.003

376 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

380 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication FASERNA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 137

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication GENERAL MYALGIAS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

386 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

390 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication APPENDECTOMY

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE QHS

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

PRODUCTION RELEASE (v12.003

392 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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)		4 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)		10 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication FLUAD QUADRIVALENT

Prophylaxis Yes ☒
No ☐

Indication FLU VACCINE

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

396 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication PAIN
(SECONDARY 2
APPENDECTOMY)

Dose per administration 5 - 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 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)	9 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

400 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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)		03 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication PIPERACILLIN TAZOBACTAM
IN DEXTROSE

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 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)		03 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication PIPERACILLIN TAZOBACTAM
IN DEXTROSE

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 3.375

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intraocular	<input type="radio"/>
	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 checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 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)	04 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication MORPHINE SOLUTION

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

406 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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) 03 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication NORMAL SALINE

Prophylaxis Yes ☒
No ☐

Indication HYDRATION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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) 03 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication IOPAMIDOL (ISOVUE-370) 76%

Prophylaxis Yes ☐
No ☒

Indication CT SCAN PREP

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

410 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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)		03 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication SODIUM CHLORIDE FLUSH
SYRINGE

Prophylaxis Yes ☒
No ☐

Indication IV FLUSH

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 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)	04 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication NORMAL SALINE SOLUTION

Prophylaxis Yes ☒
No ☐

Indication HYDRATION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS

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

PRODUCTION RELEASE (v12.003

414 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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)		03 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication HYDROCODONE
ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication MILD PAIN / APPENDICITIS

Dose per administration 5 / 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE EVERY 4 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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)		04 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication LACTATED RINGERS SOLUTION

Prophylaxis Yes ☒
No ☐

Indication HYDRATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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)		03 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication HYDROMORPHONE SOLUTION

Prophylaxis Yes ☐
No ☒

Indication SEVERE PAIN / APPENDICITIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 5 MINUTES

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

PRODUCTION RELEASE (v12.003

420 of 2861

EAB) (1725)

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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)		03 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

422 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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)		04 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) 04 SEP 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"/>

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Name of Medication _____

Prophylaxis Yes ☐
No ☐

Indication _____

Dose per administration _____

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

	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) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input 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"/>

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:59:20

Generated On: 09 Jun 2021 17:43:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Apr 2021 15:23:54

Generated On: 09 Jun 2021 17:43:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
3 SEP 2020	LAPAROSCOPIC APPENDECTOMY	Adverse Event	
03 SEP 2020	CT SCAN ABDOMINAL	Diagnostic	

US3442113

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:43:21

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

US3442113

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:43:21

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 ☐

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	07/SEP/2020 16:38
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	09/SEP/2020 13:12
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	15/SEP/2020 09:27
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	16/SEP/2020 07:56
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:00
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:41
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	02/DEC/2020 11:29
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	07/DEC/2020 10:07
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	09/FEB/2021 17:33
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:32
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

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 13 Apr 2021 15:23:55

Generated On: 09 Jun 2021 17:43:21

SAEID	USA-US017-2020-MRNA-1273-P301000001
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	16/MAR/2021 10:34
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

US3442113 (Prod: Benchmark Research - Fort Worth)

US3442113

Form: Participant Creation

Generated On: 09 Jun 2021 17:43:21

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'US3442113'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 18:09:40

US3442113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:58:06
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:12

US3442113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:58:38
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 18:09:41

US3442113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:48:18
User closed query 'Source doesn't match. Please update accordingly. ' (Site from CRA).		06 Oct 2020 19:48:16
Query 'Source doesn't match. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:03:36
User opened query 'Source doesn't match. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 19:59:18
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:12

US3442113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'SCRN'	System	01 Sep 2020 19:45:12

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:38
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 18:09:41

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:40
User entered '71'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'YEARS'	System	03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '71'	System	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:43
User entered 'Male (M)'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered 'l'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered '0'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered '0'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered '0'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered '0'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered '0'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered empty.		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered '0'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:21

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:00:50
User entered '0'		03 Sep 2020 13:52:32

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:01:08
User entered '1 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Sep 2020'	System	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2020'	System	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:01:11
User entered 'Amendment 3 (3)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:01:14
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:02:36
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:02:36
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:02:36
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:26

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:02:36
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 18:09:41

US3442113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'I'	System	01 Sep 2020 19:45:31

US3442113

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:04:07
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:31

US3442113

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:43:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:04:12
User entered 'Yes (Y)'		03 Sep 2020 13:55:58

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:11
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)	03 Sep 2020 13:57:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:57:40
Data point term sent to Coder	System	03 Sep 2020 13:56:24
User entered 'seasonal allergies'	(b) (4), (b) (6)	03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:12
User entered 'un UNK 2010'		03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:13
User entered '0'		03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:16
User entered 'Yes (Y)'		03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:18
User entered empty.		03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:19
User entered '0'		03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2010'	System	03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2010'	System	03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:56:23

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:34
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:58:45
Data point term sent to Coder	System	03 Sep 2020 13:57:25
User entered 'gerd'	(b) (4), (b) (6)	03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:39
User entered 'un UNK 2015'		03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:41
User entered '0'		03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:43
User entered 'Yes (Y)'		03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:44
User entered empty.		03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:46
User entered '0'		03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2015'	System	03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2015'	System	03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:56:38

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:58
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual disorders NEC, PT: Diplopia, LLT: Diplopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:58:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:58:46
Data point term sent to Coder	System	03 Sep 2020 13:57:25
User entered 'diplopia'	(b) (4), (b) (6)	03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:05:59
User entered 'un UNK 2019'		03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:06:01
User entered '0'		03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:06:03
User entered 'Yes (Y)'		03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:06:05
User entered empty.		03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:06:07
User entered '0'		03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2019'	System	03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2019'	System	03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:56:57

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:07:01
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)	03 Sep 2020 14:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:54:41
Data point term sent to Coder	System	03 Sep 2020 14:53:32
Coding entries removed.	(b) (4), (b) (6)	03 Sep 2020 14:53:21
User entered 'HYPOthyroidism' reason for change: Data Entry Error		03 Sep 2020 14:53:21
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:59:49
Data point term sent to Coder	System	03 Sep 2020 13:58:26
User entered 'hyperthyroidism'	(b) (4), (b) (6)	03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:07:02
User entered 'un UNK 2009'		03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:07:04
User entered '0'		03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:07:06
User entered 'Yes (Y)'		03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:07:08
User entered empty.		03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:07:10
User entered '0'		03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2009'	System	03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2009'	System	03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:57:28

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:09:58
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:59:48
Data point term sent to Coder	System	03 Sep 2020 13:58:26
User entered 'benign prostatic hyperplasia'	(b) (4), (b) (6)	03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:09:59
User entered 'un UNK 2018'		03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:01
User entered '0'		03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:02
User entered 'Yes (Y)'		03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:04
User entered empty.		03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:05
User entered '0'		03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2018'	System	03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2018'	System	03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:58:16

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:09
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)	03 Sep 2020 14:00:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:00:42
Data point term sent to Coder	System	03 Sep 2020 13:59:30
User entered 'hypertension'	(b) (4), (b) (6)	03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:11
User entered 'un UNK 2019'		03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:12
User entered '0'		03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:15
User entered 'Yes (Y)'		03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:16
User entered empty.		03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:18
User entered '0'		03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2019'	System	03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2019'	System	03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:58:31

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:10:21
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)	03 Sep 2020 14:00:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:00:41
Data point term sent to Coder	System	03 Sep 2020 13:59:30
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:11:35
User entered 'un UNK 2019'		03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:11:37
User entered '0'		03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:11:38
User entered 'Yes (Y)'		03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:11:40
User entered empty.		03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:11:44
User entered '0'		03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2019'	System	03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2019'	System	03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:58:51

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:55:21
User closed query 'Source doesn't match with the condition. Please update accordingly. ' (Site from CRA).		06 Oct 2020 19:55:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:02:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:02:42
Data point term sent to Coder	System	22 Sep 2020 20:02:04
Query 'Source doesn't match with the condition. Please update accordingly. ' answered with 'CORRECTED' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 20:01:26
Coding entries removed.		22 Sep 2020 20:01:19
User entered 'ASTHMA' reason for change: Data Entry Error		22 Sep 2020 20:01:19
User opened query 'Source doesn't match with the condition. Please update accordingly. ' (Site from CRA).		18 Sep 2020 20:09:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:00:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:00:42
Data point term sent to Coder	System	03 Sep 2020 13:59:29
User entered 'sleep apnea'	(b) (4), (b) (6)	03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:55:23
User entered 'un UNK 2012'		03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:55:25
User entered '0'		03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:55:27
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:00:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:00:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:00:08
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 13:59:14
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:55:29
User entered empty.		03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:55:31
User entered '0'		03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2012'	System	03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2012'	System	03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	03 Sep 2020 13:59:14

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:12:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Extremity deformities, PT: Foot deformity, LLT: Hammer toe - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:05:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:05:44
Data point term sent to Coder	System	03 Sep 2020 14:00:31
User entered 'hammertoe: right foot 2nd and 3rd toes'	(b) (4), (b) (6)	03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:12:51
User entered 'un UNK 2009'		03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:12:53
User entered '0'		03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:12:55
User entered 'No (N)'		03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:12:57
User entered 'un UNK 2014'		03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:12:58
User entered '0'		03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2009'	System	03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2009'	System	03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2014'	System	03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2014'	System	03 Sep 2020 13:59:55

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:13:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:35:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:35:43
Data point term sent to Coder	System	03 Sep 2020 14:01:31
User entered 'torn meniscus bl'	(b) (4), (b) (6)	03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:13:45
User entered 'un UNK 2011'		03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:13:46
User entered '0'		03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:13:48
User entered 'No (N)'		03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:13:51
User entered 'un UNK 2011'		03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:13:53
User entered '0'		03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2011'	System	03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2011'	System	03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2011'	System	03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2011'	System	03 Sep 2020 14:01:18

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:03
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Neck injury, LLT: Neck injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:53:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:53:42
Data point term sent to Coder	System	03 Sep 2020 14:02:32
User entered 'neck injury c6 c7'	(b) (4), (b) (6)	03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:09
User entered 'un UNK 1998'		03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:07
User entered '0'		03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:10
User entered 'No (N)'		03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:14
User entered 'un UNK 1998'		03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:16
User entered '0'		03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 1998'	System	03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '1998'	System	03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 1998'	System	03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '1998'	System	03 Sep 2020 14:02:13

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Please update the condition to confirm if the Polyp was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:27:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:10:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal polyps, LLT: Nasal polyps - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 16:29:41
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 16:29:41
Data point term sent to Coder	System	20 Oct 2020 16:28:54
Query 'Per DM CLR: Please update the condition to confirm if the Polyp was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 16:28:42
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:28:36
Coding entries removed.		20 Oct 2020 16:28:36
User entered 'benign NASAL POLYPS' reason for change: Data Entry Error		20 Oct 2020 16:28:36
User opened query 'Per DM CLR: Please update the condition to confirm if the Polyp was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).		19 Oct 2020 16:26:29
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 20:14:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

585 of 2861

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal polyps, LLT: Nasal polyps - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:04:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:04:44
Data point term sent to Coder	System	03 Sep 2020 14:03:42
User entered 'nasal polyps'	(b) (4), (b) (6)	03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:27
User entered 'un UNK 2014'		03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:29
User entered '0'		03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:32
User entered 'No (N)'		03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:34
User entered 'un UNK 2014'		03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:38
User entered '0'		03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2014'	System	03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2014'	System	03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2014'	System	03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2014'	System	03 Sep 2020 14:02:50

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe operation, LLT: Correction hammer toe - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:06:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:06:44
Data point term sent to Coder	System	03 Sep 2020 14:03:43
User entered 'hammertoe surgery: right foot 2nd and 3rd toe'	(b) (4), (b) (6)	03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:51
User entered 'un UNK 2014'		03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:53
User entered '0'		03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:55
User entered 'No (N)'		03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:59
User entered 'un UNK 2014'		03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:01
User entered '0'		03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2014'	System	03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2014'	System	03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2014'	System	03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2014'	System	03 Sep 2020 14:03:31

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:21:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:21:47
Data point term sent to Coder	System	03 Sep 2020 14:04:45
User entered 'bl meniscus repair'	(b) (4), (b) (6)	03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:13
User entered 'un UNK 2011'		03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:17
User entered '0'		03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:20
User entered 'No (N)'		03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:22
User entered 'un UNK 2011'		03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:23
User entered '0'		03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2011'	System	03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2011'	System	03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2011'	System	03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2011'	System	03 Sep 2020 14:03:54

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:17:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:17:48
Data point term sent to Coder	System	03 Sep 2020 14:04:45
User entered 'c6,c7 fusion'	(b) (4), (b) (6)	03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:32
User entered 'UN UNK 1998' reason for change:		03 Sep 2020 14:06:14
Data Entry Error		
User entered 'un UNK 2011'		03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:33
User entered '0'		03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:35
User entered 'No (N)'		03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:53
User entered 'UN UNK 1998' reason for change:		03 Sep 2020 14:06:14
Data Entry Error		
User entered 'un UNK 2011'		03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:55
User entered '0'		03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 1998'	System	03 Sep 2020 14:06:14
User entered 'Jan 2011'	System	03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '1998'	System	03 Sep 2020 14:06:14
User entered '2011'	System	03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 1998'	System	03 Sep 2020 14:06:14
User entered 'Jan 2011'	System	03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '1998'	System	03 Sep 2020 14:06:14
User entered '2011'	System	03 Sep 2020 14:04:16

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:16:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal polypectomy, LLT: Nasal polypectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:50:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:50:41
Data point term sent to Coder	System	03 Sep 2020 14:05:48
User entered 'nasal polyp surgery'	(b) (4), (b) (6)	03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:28
DataPoint Un-verified.	Alma Guel (b) (4)	24 Nov 2020 22:54:14
User entered 'UN UNK 2007' reason for change:	Alma Guel (b) (4)	24 Nov 2020 22:54:14
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 20:16:04
User entered 'un UNK 2014'		03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:16:06
User entered '0'		03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:16:08
User entered 'No (N)'		03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:32
DataPoint Un-verified.	Alma Guel (b) (4)	24 Nov 2020 22:54:14
User entered 'UN UNK 2007' reason for change:	Alma Guel (b) (4)	24 Nov 2020 22:54:14
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 20:16:10
User entered 'un UNK 2014'		03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:16:11
User entered '0'		03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2007'	System	24 Nov 2020 22:54:14
User entered 'Jan 2014'	System	03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2007'	System	24 Nov 2020 22:54:14
User entered '2014'	System	03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2007'	System	24 Nov 2020 22:54:14
User entered 'Jan 2014'	System	03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2007'	System	24 Nov 2020 22:54:14
User entered '2014'	System	03 Sep 2020 14:05:08

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:56:30
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) (b) (4)	01 Oct 2020 13:09:48
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 13:09:48
Data point term sent to Coder	System	01 Oct 2020 13:08:33
User entered 'Insomnia'	Alma Guel (b) (4)	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:56:31
User entered 'un UNK 2019'	Alma Guel (b) (4)	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:56:33
User entered '0'	Alma Guel (b) (4)	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:56:35
User entered 'Yes (Y)'	Alma Guel (b) (4)	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:56:37
User entered empty.	Alma Guel (b) (4)	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:56:38
User entered '0'	Alma Guel (b) (4)	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2019'	System	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2019'	System	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	01 Oct 2020 13:07:52

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:10:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 23:30:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 23:30:31
Data point term sent to Coder	System	05 Nov 2020 23:15:16
User entered 'general myalgias'	(b) (4), (b) (6)	05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:10:56
User entered 'un UNK 2019'		05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:10:58
User entered '0'		05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:11:02
User entered 'Yes (Y)'		05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:11:05
User entered empty.		05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:11:06
User entered '0'		05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2019'	System	05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2019'	System	05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	05 Nov 2020 23:14:45

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:20
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:43:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:43:53
Data point term sent to Coder	System	19 Nov 2020 21:42:25
User entered 'Erectile Dysfunction'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:22
User entered 'un UNK 2011'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:24
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:26
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:42:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:42:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:42:26
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:42:16
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:27
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:30
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2011'	System	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2011'	System	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	19 Nov 2020 21:42:16

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:45:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:45:53
Data point term sent to Coder	System	19 Nov 2020 21:44:28
User entered 'Sleep Apnea'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:43
User entered 'un Feb 2015'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:45
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:47
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:43:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:43:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:43:54
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:43:48
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:48
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:50
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Feb 2015'	System	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2015'	System	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	19 Nov 2020 21:43:48

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:14
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Basedow's disease, LLT: Graves' disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:50:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:50:51
Data point term sent to Coder	System	19 Nov 2020 21:49:35
User entered 'Graves Disease'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:20
User entered 'un UNK 2002'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:17
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:21
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:49:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:49:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:49:19
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:49:14
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:22
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:24
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2002'	System	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2002'	System	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	19 Nov 2020 21:49:14

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:30
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Structural change, deposit and degeneration of eye NEC, PT: Endocrine ophthalmopathy, LLT: Graves' ophthalmopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:53:04
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 23:53:04
Data point term sent to Coder	System	19 Nov 2020 21:50:36
User entered 'Graves Ophthalmopathy'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:31
User entered 'un UNK 2002'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:33
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:34
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:50:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:50:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:50:12
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:50:06
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:36
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:28:37
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2002'	System	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2002'	System	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	19 Nov 2020 21:50:06

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal polypectomy, LLT: Nasal polypectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:56:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:56:06
Data point term sent to Coder	System	24 Nov 2020 22:55:32
User entered 'NASAL POLYP SURGERY'	Alma Guel (b) (4)	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:02
User entered 'un UNK 2003'	Alma Guel (b) (4)	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:03
User entered '0'	Alma Guel (b) (4)	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:04
User entered 'No (N)'	Alma Guel (b) (4)	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:06
User entered 'un UNK 2003'	Alma Guel (b) (4)	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:07
User entered '0'	Alma Guel (b) (4)	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2003'	System	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2003'	System	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 2003'	System	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '2003'	System	24 Nov 2020 22:54:41

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal polypectomy, LLT: Nasal polypectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:56:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:56:06
Data point term sent to Coder	System	24 Nov 2020 22:55:32
User entered 'NASAL POLYP SURGERY'	Alma Guel (b) (4)	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:11
User entered 'un UNK 1995'	Alma Guel (b) (4)	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:12
User entered '0'	Alma Guel (b) (4)	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:14
User entered 'No (N)'	Alma Guel (b) (4)	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:15
User entered 'un UNK 1995'	Alma Guel (b) (4)	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:43:17
User entered '0'	Alma Guel (b) (4)	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 1995'	System	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '1995'	System	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'Jan 1995'	System	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '1995'	System	24 Nov 2020 22:54:58

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:18:56
User entered 'Yes (Y)'		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:18:58
User entered '1 Sep 2020'		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:04
User entered '13:28'		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '1 Sep 2020 13:28'	System	03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:07
User entered '68.5' in		03 Sep 2020 13:54:43
DataPoint set to visible.	System	01 Sep 2020 19:45:31

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:09
User entered '192' lb		03 Sep 2020 13:54:43
DataPoint set to visible.	System	01 Sep 2020 19:45:31

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '28.82903'	System	03 Sep 2020 13:54:43
DataPoint set to visible.	System	01 Sep 2020 19:45:31

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'kg/m2'	System	03 Sep 2020 13:54:43
DataPoint set to visible.	System	01 Sep 2020 19:45:31

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:22
User entered missing code ND - Not Done.		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:22
User entered empty.		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:22
User entered empty.		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:22
User entered missing code ND - Not Done.		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'bpm'	System	03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:22
User entered missing code ND - Not Done.		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'breaths/min'	System	03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:22
User entered missing code ND - Not Done.		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'mmHg'	System	03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:22
User entered missing code ND - Not Done.		03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'mmHg'	System	03 Sep 2020 13:54:43

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34

US3442113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34

US3442113

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:19:26
User entered 'Yes (Y)'		03 Sep 2020 14:07:18

US3442113

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:21:13
User entered '1 Sep 2020'		03 Sep 2020 14:07:18

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'No (N)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'Yes (Y)'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'daily errands in the community'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered '0'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered '0'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered '0'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered '0'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered 'I'		03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 13:53:32

US3442113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:22:58
User entered empty.		03 Sep 2020 13:53:32

US3442113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:23:21
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:45

US3442113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:23:23
User entered '1 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:45

US3442113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:03:51
User closed query 'Source doesn't match. Please update accordingly. ' (Site from CRA).		06 Oct 2020 20:03:49
Query 'Source doesn't match. Please update accordingly. ' answered with 'source updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:09:46
User opened query 'Source doesn't match. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 20:23:48
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:45:45

US3442113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'VISIT1'	System	01 Sep 2020 19:45:45

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:24:17
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 19:14:48

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:24:36
User entered '188306'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 19:14:48

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:24:37
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 19:14:48

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:39:07
DataPoint Un-verified.		06 Oct 2020 19:56:58
DataPoint Verified.		06 Oct 2020 19:51:09
User entered 'No (N)'		03 Sep 2020 13:53:48

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:24:46
User entered 'No (N)'		03 Sep 2020 13:53:48

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:24:48
User entered 'No (N)'		03 Sep 2020 13:53:48

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:25:02
User entered 'No (N)'		03 Sep 2020 13:53:48

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:25:04
User entered 'No (N)'		03 Sep 2020 13:53:48

US3442113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:21

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:51:13
User entered 'No (N)'		22 Sep 2020 20:02:54
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:59:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:59:37

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:28:22
User entered missing code ND - Not Done.		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:28:24
User entered missing code ND - Not Done.		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:28:22
User entered missing code ND - Not Done.		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:28:24
User entered missing code ND - Not Done.		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User accepted default value 'Pre-Dose (PREDOSE)'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:29:45
User entered 'Yes (Y)'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:29:47
User entered '1 Sep 2020'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:29:50
User entered '13:28'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '1 Sep 2020 13:28'	System	03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per CDM: Thank you for your response. However, please indicate if the value is CS/NCS per PI. Thank you ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 10:05:33
Query 'Per CDM: Thank you for your response. However, please indicate if the value is CS/NCS per PI. Thank you ' answered with 'ncs' (Site from DM). User opened query 'Per CDM: Thank you for your response. However, please indicate if the value is CS/NCS per PI. Thank you ' (Site from DM). User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). DataPoint Un-verified.		06 Oct 2020 19:52:57
		30 Sep 2020 17:23:49
		21 Sep 2020 18:20:45
		21 Sep 2020 18:20:42
	(b) (4), (b) (6)	18 Sep 2020 20:30:07
DataPoint Verified.		18 Sep 2020 20:29:53
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'temp is correct as entered. temp was rechecked and remained the same.' (Site from System).		17 Sep 2020 18:03:39
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:24:49
User entered '96.7' F	(b) (4), (b) (6)	03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:33:13
User entered 'Oral (Oral)'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:33:15
User entered empty.		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:33:17
User entered '56'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'bpm'	System	03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:33:20
User entered '14'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'breaths/min'	System	03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:33:37
User entered '137'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'mmHg'	System	03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:33:39
User entered '67'		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'mmHg'	System	03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:28:22
User entered missing code ND - Not Done.		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:28:24
User entered missing code ND - Not Done.		03 Sep 2020 13:55:27

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User accepted default value 'Post-Dose (POSTDOSE)'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:33:54
User entered 'Yes (Y)'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:42:42
User entered '1 Sep 2020'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:42:44
User entered '15:06'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '1 Sep 2020 15:06'	System	03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		07 Apr 2021 13:53:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per CDM: Thank you for your response. However, please indicate if the value is CS/NCS per PI. Thank you ' (Site from DM).	(b) (4)	07 Oct 2020 10:05:39
Query 'Per CDM: Thank you for your response. However, please indicate if the value is CS/NCS per PI. Thank you ' answered with 'ncs' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 17:24:02
User opened query 'Per CDM: Thank you for your response. However, please indicate if the value is CS/NCS per PI. Thank you ' (Site from DM).		21 Sep 2020 18:20:58
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		21 Sep 2020 18:20:54
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'temp is correct as entered. temp was rechecked and remained the same.' (Site from System).		17 Sep 2020 18:04:01
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:24:49
User entered '96.1' F	(b) (4), (b) (6)	03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:43:02
User entered 'Oral (Oral)'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:43:03
User entered empty.		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:43:05
User entered '47'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'bpm'	System	03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:43:08
User entered '14'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'breaths/min'	System	03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:43:14
User entered '133'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'mmHg'	System	03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:43:18
User entered '70'		03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'mmHg'	System	03 Sep 2020 14:14:11

US3442113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:34:12
User entered 'No (N)'		03 Sep 2020 13:55:32

US3442113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:34:14
User entered empty.		03 Sep 2020 13:55:32

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:41:49
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:42:05
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:42:05
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:42:05
User entered '1 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:42:05
User entered '14:36'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '1 Sep 2020 14:36'	System	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:42:05
User entered 'Left Arm (LEFT ARM)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		18 Sep 2020 20:42:05
User entered 'ONCE'	System	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 19:46:23

US3442113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:36:22
User entered 'Yes (Y)'		03 Sep 2020 14:07:54

US3442113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:36:26
User entered '1 Sep 2020'		03 Sep 2020 14:07:54

US3442113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:36:33
User entered '14:05'		03 Sep 2020 14:07:54

US3442113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '1 Sep 2020 14:05'	System	03 Sep 2020 14:07:54

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:43:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:36:40
User entered '1 Sep 2020'		03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:36:50
User entered 'Yes (Y)'		03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:36:53
User entered '14:09'		03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered '1 Sep 2020 14:09'	System	03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:07:44
User entered 'No (N)'		03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:07:46
User entered empty.		03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered empty.	System	03 Sep 2020 14:08:29

US3442113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:45:27
User entered 'Yes (Y)'		03 Sep 2020 14:08:35

US3442113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered '1'	System	03 Sep 2020 14:08:35

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:14:03', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8441388f-64c5-4cac-b814-b557f2965646' User entered 'Yes (Y)'	System	01 Sep 2020 20:14:33
	System	01 Sep 2020 20:14:33

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:14:15', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8441388f-64c5-4cac-b814-b557f2965646' User entered '96.1'	System	01 Sep 2020 20:14:33
	System	01 Sep 2020 20:14:33

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:14:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8441388f-64c5-4cac-b814-b557f2965646'	System	01 Sep 2020 20:14:33
User entered 'No (N)'	System	01 Sep 2020 20:14:33

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:14:30', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8441388f-64c5-4cac-b814-b557f2965646' User entered '01 Sep 2020 15:14'	System	01 Sep 2020 20:14:33
	System	01 Sep 2020 20:14:33

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 14:56'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 17:26'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 18:21'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 2'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:35:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f17542a-9f98-4e04-b324-bfabccaeb7b5' User entered 'Yes (Y)'	System	02 Sep 2020 22:37:16
	System	02 Sep 2020 22:37:16

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:35:59', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f17542a-9f98-4e04-b324-bfabccaeb7b5' User entered '98.3'	System	02 Sep 2020 22:37:16
	System	02 Sep 2020 22:37:16

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:36:06', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f17542a-9f98-4e04-b324-bfabccaeb7b5'	System	02 Sep 2020 22:37:16
User entered 'Yes (Y)'	System	02 Sep 2020 22:37:16

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted. med taken is a med the subject normally takes for aches and pains. Subject took naproxen for hip pain' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 14:26:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Sep 2020 15:11:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:36:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f17542a-9f98-4e04-b324-bfabccaeb7b5'	System	02 Sep 2020 22:37:16
User entered '1'	System	02 Sep 2020 22:37:16

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:36:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f17542a-9f98-4e04-b324-bfabccaeb7b5' User entered '0'	System	02 Sep 2020 22:37:16
	System	02 Sep 2020 22:37:16

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:37:13', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f17542a-9f98-4e04-b324-bfabccaeb7b5' User entered '02 Sep 2020 17:37'	System	02 Sep 2020 22:37:16
	System	02 Sep 2020 22:37:16

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 3'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:36:36', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5245bae0-9431-4231-a867-854458c7b354' User entered 'Yes (Y)'	System	03 Sep 2020 19:37:57
	System	03 Sep 2020 19:37:57

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:36:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5245bae0-9431-4231-a867-854458c7b354' User entered '98.5'	System	03 Sep 2020 19:37:57
	System	03 Sep 2020 19:37:57

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:37:14', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5245bae0-9431-4231-a867-854458c7b354'	System	03 Sep 2020 19:37:57
User entered 'Yes (Y)'	System	03 Sep 2020 19:37:57

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		04 Sep 2020 14:26:16
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed with subject that pain medication was taken for hip pain, not injection site pain.' (Site from System).	Tisha Davis (b) (4) (b) (4)	04 Sep 2020 13:02:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Sep 2020 19:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:37:26', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5245bae0-9431-4231-a867-854458c7b354'	System	03 Sep 2020 19:37:57
User entered '1'	System	03 Sep 2020 19:37:57

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:37:26', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5245bae0-9431-4231-a867-854458c7b354' User entered '0'	System	03 Sep 2020 19:37:57
	System	03 Sep 2020 19:37:57

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:37:54', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5245bae0-9431-4231-a867-854458c7b354'	System	03 Sep 2020 19:37:57
User entered '03 Sep 2020 14:37'	System	03 Sep 2020 19:37:57

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 4'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:03:02', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '519643c9-9a14-423c-9af7-ce7e68e4824d' User entered 'Yes (Y)'	System	05 Sep 2020 01:04:04
	System	05 Sep 2020 01:04:04

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:01:58', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '519643c9-9a14-423c-9af7-ce7e68e4824d' User entered '96.2'	System	05 Sep 2020 01:04:04
	System	05 Sep 2020 01:04:04

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:02:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '519643c9-9a14-423c-9af7-ce7e68e4824d'	System	05 Sep 2020 01:04:04
User entered 'Yes (Y)'	System	05 Sep 2020 01:04:04

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'meds added. logs updated' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 09:44:31
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 23:24:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:03:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '519643c9-9a14-423c-9af7-ce7e68e4824d'	System	05 Sep 2020 01:04:04
User entered '1'	System	05 Sep 2020 01:04:04

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:03:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '519643c9-9a14-423c-9af7-ce7e68e4824d' User entered '0'	System	05 Sep 2020 01:04:04
	System	05 Sep 2020 01:04:04

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:03:56', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '519643c9-9a14-423c-9af7-ce7e68e4824d' User entered '04 Sep 2020 20:03'	System	05 Sep 2020 01:04:04
	System	05 Sep 2020 01:04:04

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 5'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T20:00:05', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1c273822-1d6c-4b3b-a062-a5f828afcb33' User entered 'Yes (Y)'	System	06 Sep 2020 01:00:38
	System	06 Sep 2020 01:00:38

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T20:00:14', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1c273822-1d6c-4b3b-a062-a5f828afcb33' User entered '97.1'	System	06 Sep 2020 01:00:38
	System	06 Sep 2020 01:00:38

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T20:00:23', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1c273822-1d6c-4b3b-a062-a5f828afcb33'	System	06 Sep 2020 01:00:38
User entered 'Yes (Y)'	System	06 Sep 2020 01:00:38

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'meds added. logs updated.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 09:44:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Sep 2020 01:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T20:00:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1c273822-1d6c-4b3b-a062-a5f828afcb33'	System	06 Sep 2020 01:00:38
User entered '1'	System	06 Sep 2020 01:00:38

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T20:00:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1c273822-1d6c-4b3b-a062-a5f828afcb33' User entered '0'	System	06 Sep 2020 01:00:38
	System	06 Sep 2020 01:00:38

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T20:00:36', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1c273822-1d6c-4b3b-a062-a5f828afcb33'	System	06 Sep 2020 01:00:38
User entered '05 Sep 2020 20:00'	System	06 Sep 2020 01:00:38

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 6'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:04', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ce55d3da-6a18-4e32-9064-2cb239165604' User entered 'Yes (Y)'	System	07 Sep 2020 16:25:37
	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:13', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ce55d3da-6a18-4e32-9064-2cb239165604' User entered '96.7'	System	07 Sep 2020 16:25:37
	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:25', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ce55d3da-6a18-4e32-9064-2cb239165604'	System	07 Sep 2020 16:25:37
User entered 'Yes (Y)'	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'meds added. logs updated.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 09:44:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Sep 2020 16:25:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:28', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ce55d3da-6a18-4e32-9064-2cb239165604'	System	07 Sep 2020 16:25:37
User entered '1'	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:28', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ce55d3da-6a18-4e32-9064-2cb239165604' User entered '0'	System	07 Sep 2020 16:25:37
	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:35', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ce55d3da-6a18-4e32-9064-2cb239165604' User entered '07 Sep 2020 11:25'	System	07 Sep 2020 16:25:37
	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 7'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	07 Sep 2020 16:25:37
User entered 'Day 8'	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:33:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6b539da-94c1-49cd-8ab4-d164b8d939f8' User entered 'Yes (Y)'	System	08 Sep 2020 22:38:03
	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:37:40', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6b539da-94c1-49cd-8ab4-d164b8d939f8' User entered '97.0'	System	08 Sep 2020 22:38:03
	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:37:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6b539da-94c1-49cd-8ab4-d164b8d939f8' User entered 'Yes (Y)'	System	08 Sep 2020 22:38:03
	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'meds added. logs updated.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 09:44:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 22:38:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:37:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6b539da-94c1-49cd-8ab4-d164b8d939f8'	System	08 Sep 2020 22:38:03
User entered '1'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:37:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6b539da-94c1-49cd-8ab4-d164b8d939f8' User entered '0'	System	08 Sep 2020 22:38:03
	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:37:57', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6b539da-94c1-49cd-8ab4-d164b8d939f8' User entered '08 Sep 2020 17:37'	System	08 Sep 2020 22:38:03
	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	08 Sep 2020 22:38:03
User entered 'Day 9'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-09T18:16:13', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '170c1ec6-71f0-441e-b758-34b42c668c9a' User entered 'Yes (Y)'	System	09 Sep 2020 23:16:53
	System	09 Sep 2020 23:16:53

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-09T18:16:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '170c1ec6-71f0-441e-b758-34b42c668c9a' User entered '96.5'	System	09 Sep 2020 23:16:53
	System	09 Sep 2020 23:16:53

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-09T18:16:29', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '170c1ec6-71f0-441e-b758-34b42c668c9a'	System	09 Sep 2020 23:16:53
User entered 'No (N)'	System	09 Sep 2020 23:16:53

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-09T18:16:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '170c1ec6-71f0-441e-b758-34b42c668c9a'	System	09 Sep 2020 23:16:53
User entered '09 Sep 2020 18:16'	System	09 Sep 2020 23:16:53

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:14:59', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'be18d2e2-4410-4bc8-82a8-f668304539c5' User entered 'None (1)'	System	01 Sep 2020 20:15:23
	System	01 Sep 2020 20:15:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:15:04', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'be18d2e2-4410-4bc8-82a8-f668304539c5' User entered 'No (N)'	System	01 Sep 2020 20:15:23
	System	01 Sep 2020 20:15:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:15:08', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'be18d2e2-4410-4bc8-82a8-f668304539c5' User entered 'No (N)'	System	01 Sep 2020 20:15:23
	System	01 Sep 2020 20:15:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:15:15', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'be18d2e2-4410-4bc8-82a8-f668304539c5'	System	01 Sep 2020 20:15:23
User entered 'None (1)'	System	01 Sep 2020 20:15:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-01T15:15:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'be18d2e2-4410-4bc8-82a8-f668304539c5' User entered '01 Sep 2020 15:15'	System	01 Sep 2020 20:15:23
	System	01 Sep 2020 20:15:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 14:56'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 17:26'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:01:59', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '623079bd-ccfe-4e02-9f56-be39dc012488'	System	02 Sep 2020 15:06:05
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 15:06:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:02:14', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '623079bd-ccfe-4e02-9f56-be39dc012488' User entered 'No (N)'	System	02 Sep 2020 15:06:05
	System	02 Sep 2020 15:06:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:02:38', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '623079bd-ccfe-4e02-9f56-be39dc012488'	System	02 Sep 2020 15:06:05
User entered 'Yes (Y)'	System	02 Sep 2020 15:06:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:04:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '623079bd-ccfe-4e02-9f56-be39dc012488' User entered '5'	System	02 Sep 2020 15:06:05
	System	02 Sep 2020 15:06:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:05:23', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '623079bd-ccfe-4e02-9f56-be39dc012488'	System	02 Sep 2020 15:06:05
User entered 'None (1)'	System	02 Sep 2020 15:06:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:05:47', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '623079bd-ccfe-4e02-9f56-be39dc012488' User entered '02 Sep 2020 10:05'	System	02 Sep 2020 15:06:05
	System	02 Sep 2020 15:06:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 18:21'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 2'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:40:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f4a1d39-df3d-4f59-9312-c251d74b31ab' User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 22:41:07
	System	02 Sep 2020 22:41:07

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:38:24', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f4a1d39-df3d-4f59-9312-c251d74b31ab' User entered 'No (N)'	System	02 Sep 2020 22:41:07
	System	02 Sep 2020 22:41:07

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:38:28', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f4a1d39-df3d-4f59-9312-c251d74b31ab' User entered 'Yes (Y)'	System	02 Sep 2020 22:41:07
	System	02 Sep 2020 22:41:07

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:39:03', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f4a1d39-df3d-4f59-9312-c251d74b31ab' User entered '8'	System	02 Sep 2020 22:41:07
	System	02 Sep 2020 22:41:07

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:40:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f4a1d39-df3d-4f59-9312-c251d74b31ab' User entered 'None (1)'	System	02 Sep 2020 22:41:07
	System	02 Sep 2020 22:41:07

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:41:02', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f4a1d39-df3d-4f59-9312-c251d74b31ab' User entered '02 Sep 2020 17:41'	System	02 Sep 2020 22:41:07
	System	02 Sep 2020 22:41:07

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 3'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:40:09', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ba58d53b-eccd-4bde-813e-2d30020cdd73'	System	03 Sep 2020 19:41:35
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 19:41:35

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:40:25', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ba58d53b-eccd-4bde-813e-2d30020cdd73' User entered 'Yes (Y)'	System	03 Sep 2020 19:41:35
	System	03 Sep 2020 19:41:35

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:40:57', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ba58d53b-eccd-4bde-813e-2d30020cdd73' User entered '6'	System	03 Sep 2020 19:41:35
	System	03 Sep 2020 19:41:35

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:41:01', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ba58d53b-eccd-4bde-813e-2d30020cdd73' User entered 'Yes (Y)'	System	03 Sep 2020 19:41:35
	System	03 Sep 2020 19:41:35

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:41:08', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ba58d53b-eccd-4bde-813e-2d30020cdd73' User entered '5'	System	03 Sep 2020 19:41:35
	System	03 Sep 2020 19:41:35

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:41:20', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ba58d53b-eccd-4bde-813e-2d30020cdd73'	System	03 Sep 2020 19:41:35
User entered 'None (1)'	System	03 Sep 2020 19:41:35

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:41:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ba58d53b-eccd-4bde-813e-2d30020cdd73' User entered '03 Sep 2020 14:41'	System	03 Sep 2020 19:41:35
	System	03 Sep 2020 19:41:35

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 4'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:04:10', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '3b7cf4d6-548b-49e3-87dc-ad9934953082'	System	05 Sep 2020 01:05:09
User entered 'None (1)'	System	05 Sep 2020 01:05:09

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:04:18', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '3b7cf4d6-548b-49e3-87dc-ad9934953082' User entered 'No (N)'	System	05 Sep 2020 01:05:09
	System	05 Sep 2020 01:05:09

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:04:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '3b7cf4d6-548b-49e3-87dc-ad9934953082' User entered 'No (N)'	System	05 Sep 2020 01:05:09
	System	05 Sep 2020 01:05:09

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:04:56', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '3b7cf4d6-548b-49e3-87dc-ad9934953082' User entered 'None (1)'	System	05 Sep 2020 01:05:09
	System	05 Sep 2020 01:05:09

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:05:06', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '3b7cf4d6-548b-49e3-87dc-ad9934953082' User entered '04 Sep 2020 20:05'	System	05 Sep 2020 01:05:09
	System	05 Sep 2020 01:05:09

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 5'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:57:11', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b89b7497-9fda-483a-a25b-ca3a2d58e55d'	System	06 Sep 2020 00:57:46
User entered 'None (1)'	System	06 Sep 2020 00:57:46

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:57:15', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b89b7497-9fda-483a-a25b-ca3a2d58e55d' User entered 'No (N)'	System	06 Sep 2020 00:57:46
	System	06 Sep 2020 00:57:46

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:57:19', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b89b7497-9fda-483a-a25b-ca3a2d58e55d' User entered 'No (N)'	System	06 Sep 2020 00:57:46
	System	06 Sep 2020 00:57:46

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:57:34', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b89b7497-9fda-483a-a25b-ca3a2d58e55d'	System	06 Sep 2020 00:57:46
User entered 'None (1)'	System	06 Sep 2020 00:57:46

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:57:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b89b7497-9fda-483a-a25b-ca3a2d58e55d' User entered '05 Sep 2020 19:57'	System	06 Sep 2020 00:57:46
	System	06 Sep 2020 00:57:46

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 6'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f736710d-c7af-4c2c-9327-b590ecd82f80'	System	07 Sep 2020 16:26:05
User entered 'None (1)'	System	07 Sep 2020 16:26:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f736710d-c7af-4c2c-9327-b590ecd82f80'	System	07 Sep 2020 16:26:05
User entered 'No (N)'	System	07 Sep 2020 16:26:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:52', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f736710d-c7af-4c2c-9327-b590ecd82f80'	System	07 Sep 2020 16:26:05
User entered 'No (N)'	System	07 Sep 2020 16:26:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:25:58', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f736710d-c7af-4c2c-9327-b590ecd82f80'	System	07 Sep 2020 16:26:05
User entered 'None (1)'	System	07 Sep 2020 16:26:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:26:03', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f736710d-c7af-4c2c-9327-b590ecd82f80'	System	07 Sep 2020 16:26:05
User entered '07 Sep 2020 11:26'	System	07 Sep 2020 16:26:05

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 7'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 14:56'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 17:26'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:00:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f012040-bb7f-485d-b19c-99051dd6797d' User entered 'None (0)'	System	02 Sep 2020 15:01:37
	System	02 Sep 2020 15:01:37

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T09:59:09', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f012040-bb7f-485d-b19c-99051dd6797d' User entered 'None (0)'	System	02 Sep 2020 15:01:37
	System	02 Sep 2020 15:01:37

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T09:59:16', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f012040-bb7f-485d-b19c-99051dd6797d' User entered 'None (0)'	System	02 Sep 2020 15:01:37
	System	02 Sep 2020 15:01:37

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:01:13', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f012040-bb7f-485d-b19c-99051dd6797d'	System	02 Sep 2020 15:01:37
User entered 'No interference with activity (1)'	System	02 Sep 2020 15:01:37

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T09:59:40', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f012040-bb7f-485d-b19c-99051dd6797d' User entered 'None (0)'	System	02 Sep 2020 15:01:37
	System	02 Sep 2020 15:01:37

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T09:59:55', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f012040-bb7f-485d-b19c-99051dd6797d' User entered 'None (0)'	System	02 Sep 2020 15:01:37
	System	02 Sep 2020 15:01:37

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:00:04', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f012040-bb7f-485d-b19c-99051dd6797d' User entered 'No (N)'	System	02 Sep 2020 15:01:37
	System	02 Sep 2020 15:01:37

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T10:01:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f012040-bb7f-485d-b19c-99051dd6797d' User entered '02 Sep 2020 10:01'	System	02 Sep 2020 15:01:37
	System	02 Sep 2020 15:01:37

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Sep 2020 18:21'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 2'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:41:15', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a900da6a-c32a-4e38-a865-89731dfa3659' User entered 'None (0)'	System	02 Sep 2020 22:42:44
	System	02 Sep 2020 22:42:44

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:41:26', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a900da6a-c32a-4e38-a865-89731dfa3659' User entered 'None (0)'	System	02 Sep 2020 22:42:44
	System	02 Sep 2020 22:42:44

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:41:45', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a900da6a-c32a-4e38-a865-89731dfa3659' User entered 'None (0)'	System	02 Sep 2020 22:42:44
	System	02 Sep 2020 22:42:44

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:41:52', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a900da6a-c32a-4e38-a865-89731dfa3659' User entered 'None (0)'	System	02 Sep 2020 22:42:44
	System	02 Sep 2020 22:42:44

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:41:56', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a900da6a-c32a-4e38-a865-89731dfa3659' User entered 'None (0)'	System	02 Sep 2020 22:42:44
	System	02 Sep 2020 22:42:44

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:42:02', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a900da6a-c32a-4e38-a865-89731dfa3659' User entered 'None (0)'	System	02 Sep 2020 22:42:44
	System	02 Sep 2020 22:42:44

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:42:15', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a900da6a-c32a-4e38-a865-89731dfa3659'	System	02 Sep 2020 22:42:44
User entered 'No (N)'	System	02 Sep 2020 22:42:44

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-02T17:42:42', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a900da6a-c32a-4e38-a865-89731dfa3659' User entered '02 Sep 2020 17:42'	System	02 Sep 2020 22:42:44
	System	02 Sep 2020 22:42:44

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 3'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:38:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ef467781-82fc-4822-8f27-b78f923d0aa7' User entered 'None (0)'	System	03 Sep 2020 19:39:41
	System	03 Sep 2020 19:39:41

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:38:37', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ef467781-82fc-4822-8f27-b78f923d0aa7' User entered 'None (0)'	System	03 Sep 2020 19:39:41
	System	03 Sep 2020 19:39:41

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:38:53', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ef467781-82fc-4822-8f27-b78f923d0aa7' User entered 'None (0)'	System	03 Sep 2020 19:39:41
	System	03 Sep 2020 19:39:41

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:38:56', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ef467781-82fc-4822-8f27-b78f923d0aa7' User entered 'None (0)'	System	03 Sep 2020 19:39:41
	System	03 Sep 2020 19:39:41

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:39:01', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ef467781-82fc-4822-8f27-b78f923d0aa7' User entered 'None (0)'	System	03 Sep 2020 19:39:41
	System	03 Sep 2020 19:39:41

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:39:03', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ef467781-82fc-4822-8f27-b78f923d0aa7' User entered 'None (0)'	System	03 Sep 2020 19:39:41
	System	03 Sep 2020 19:39:41

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:39:18', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ef467781-82fc-4822-8f27-b78f923d0aa7' User entered 'Yes (Y)'	System	03 Sep 2020 19:39:41
	System	03 Sep 2020 19:39:41

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-03T14:39:37', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'ef467781-82fc-4822-8f27-b78f923d0aa7' User entered '03 Sep 2020 14:39'	System	03 Sep 2020 19:39:41
	System	03 Sep 2020 19:39:41

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 4'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:05:23', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '47ab0a27-fa79-4063-9724-9ad35c188ec9' User entered 'None (0)'	System	05 Sep 2020 01:06:52
	System	05 Sep 2020 01:06:52

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:05:47', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '47ab0a27-fa79-4063-9724-9ad35c188ec9'	System	05 Sep 2020 01:06:52
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:06:52

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:06:03', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '47ab0a27-fa79-4063-9724-9ad35c188ec9' User entered 'None (0)'	System	05 Sep 2020 01:06:52
	System	05 Sep 2020 01:06:52

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:06:09', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '47ab0a27-fa79-4063-9724-9ad35c188ec9' User entered 'None (0)'	System	05 Sep 2020 01:06:52
	System	05 Sep 2020 01:06:52

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:06:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '47ab0a27-fa79-4063-9724-9ad35c188ec9' User entered 'None (0)'	System	05 Sep 2020 01:06:52
	System	05 Sep 2020 01:06:52

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:06:26', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '47ab0a27-fa79-4063-9724-9ad35c188ec9' User entered 'None (0)'	System	05 Sep 2020 01:06:52
	System	05 Sep 2020 01:06:52

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:06:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '47ab0a27-fa79-4063-9724-9ad35c188ec9' User entered 'No (N)'	System	05 Sep 2020 01:06:52
	System	05 Sep 2020 01:06:52

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-04T20:06:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '47ab0a27-fa79-4063-9724-9ad35c188ec9' User entered '04 Sep 2020 20:06'	System	05 Sep 2020 01:06:52
	System	05 Sep 2020 01:06:52

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 5'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:58:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1fd20c4c-7bef-40ad-8268-4beb8ee6d2dd' User entered 'None (0)'	System	06 Sep 2020 00:59:58
	System	06 Sep 2020 00:59:58

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:59:04', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1fd20c4c-7bef-40ad-8268-4beb8ee6d2dd'	System	06 Sep 2020 00:59:58
User entered 'Some interference with activity (2)'	System	06 Sep 2020 00:59:58

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:59:11', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1fd20c4c-7bef-40ad-8268-4beb8ee6d2dd'	System	06 Sep 2020 00:59:58
User entered 'Some interference with activity (2)'	System	06 Sep 2020 00:59:58

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:59:15', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1fd20c4c-7bef-40ad-8268-4beb8ee6d2dd'	System	06 Sep 2020 00:59:58
User entered 'Some interference with activity (2)'	System	06 Sep 2020 00:59:58

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:59:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1fd20c4c-7bef-40ad-8268-4beb8ee6d2dd' User entered 'None (0)'	System	06 Sep 2020 00:59:58
	System	06 Sep 2020 00:59:58

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:59:24', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1fd20c4c-7bef-40ad-8268-4beb8ee6d2dd' User entered 'None (0)'	System	06 Sep 2020 00:59:58
	System	06 Sep 2020 00:59:58

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:59:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1fd20c4c-7bef-40ad-8268-4beb8ee6d2dd' User entered 'No (N)'	System	06 Sep 2020 00:59:58
	System	06 Sep 2020 00:59:58

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-05T19:59:56', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1fd20c4c-7bef-40ad-8268-4beb8ee6d2dd' User entered '05 Sep 2020 19:59'	System	06 Sep 2020 00:59:58
	System	06 Sep 2020 00:59:58

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 6'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:26:12', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b572ed3b-451c-4732-9251-e99e8ad29c7d' User entered 'None (0)'	System	07 Sep 2020 16:27:11
	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:26:29', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b572ed3b-451c-4732-9251-e99e8ad29c7d' User entered 'Some interference with activity (2)'	System	07 Sep 2020 16:27:11
	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:26:37', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b572ed3b-451c-4732-9251-e99e8ad29c7d'	System	07 Sep 2020 16:27:11
User entered 'Some interference with activity (2)'	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:26:45', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b572ed3b-451c-4732-9251-e99e8ad29c7d' User entered 'None (0)'	System	07 Sep 2020 16:27:11
	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:26:50', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b572ed3b-451c-4732-9251-e99e8ad29c7d' User entered 'None (0)'	System	07 Sep 2020 16:27:11
	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:26:53', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b572ed3b-451c-4732-9251-e99e8ad29c7d' User entered 'None (0)'	System	07 Sep 2020 16:27:11
	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:27:01', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b572ed3b-451c-4732-9251-e99e8ad29c7d' User entered 'No (N)'	System	07 Sep 2020 16:27:11
	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-07T11:27:07', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b572ed3b-451c-4732-9251-e99e8ad29c7d' User entered '07 Sep 2020 11:27'	System	07 Sep 2020 16:27:11
	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 7'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	07 Sep 2020 16:27:11
User entered 'Day 8'	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:38:59', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5dc1f8c8-37ad-4ebc-abd1-b3273082332d' User entered 'Some interference with activity (2)'	System	08 Sep 2020 22:39:08
	System	08 Sep 2020 22:39:08

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:39:02', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5dc1f8c8-37ad-4ebc-abd1-b3273082332d' User entered '08 Sep 2020 17:39'	System	08 Sep 2020 22:39:08
	System	08 Sep 2020 22:39:08

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	08 Sep 2020 22:39:08
User entered 'Day 9'	System	08 Sep 2020 22:39:08

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-09T18:17:01', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '37d20035-8a21-4ce6-b8cf-9b481e6718b1'	System	09 Sep 2020 23:17:17
User entered 'No interference with activity (1)'	System	09 Sep 2020 23:17:17

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-09T18:17:15', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '37d20035-8a21-4ce6-b8cf-9b481e6718b1' User entered '09 Sep 2020 18:17'	System	09 Sep 2020 23:17:17
	System	09 Sep 2020 23:17:17

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:39:08

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:39:08

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	08 Sep 2020 22:39:08
User entered 'Day 10'	System	08 Sep 2020 22:39:08

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-10T20:02:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f8ef927f-18c5-4bca-8f00-2a67ca72fee9' User entered 'None (0)'	System	12 Sep 2020 12:36:03
	System	12 Sep 2020 12:36:03

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-10T20:02:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f8ef927f-18c5-4bca-8f00-2a67ca72fee9' User entered '10 Sep 2020 20:02'	System	12 Sep 2020 12:36:03
	System	12 Sep 2020 12:36:03

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:39:08

US3442113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:39:08

US3442113

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	07 Sep 2020 16:27:11
User entered 'Day 8'	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:43:21

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:39:11', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c6234de6-9e8a-4ada-a6c4-3146ca7b92ce' User entered 'None (0)'	System	08 Sep 2020 22:39:17
	System	08 Sep 2020 22:39:17

US3442113

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:39:14', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c6234de6-9e8a-4ada-a6c4-3146ca7b92ce' User entered '08 Sep 2020 17:39'	System	08 Sep 2020 22:39:17
	System	08 Sep 2020 22:39:17

US3442113

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	07 Sep 2020 16:25:37
User entered 'Day 8'	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:39:25', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '3eccf580-c6bd-43e0-89a4-6d6ffe61221b' User entered 'No (N)'	System	08 Sep 2020 22:39:33
	System	08 Sep 2020 22:39:33

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-08T17:39:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '3eccf580-c6bd-43e0-89a4-6d6ffe61221b' User entered '08 Sep 2020 17:39'	System	08 Sep 2020 22:39:33
	System	08 Sep 2020 22:39:33

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:25:37

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	08 Sep 2020 22:38:03
User entered 'Day 9'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-09T18:17:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7f275888-ec73-4e14-be63-6a98da816c7f' User entered 'No (N)'	System	09 Sep 2020 23:17:28
	System	09 Sep 2020 23:17:28

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-09T18:17:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7f275888-ec73-4e14-be63-6a98da816c7f' User entered '09 Sep 2020 18:17'	System	09 Sep 2020 23:17:28
	System	09 Sep 2020 23:17:28

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	08 Sep 2020 22:38:03
User entered 'Day 10'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-10T20:02:50', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5eaff9ce-f173-4665-a383-e2570bc492da' User entered 'No (N)'	System	12 Sep 2020 12:36:04
	System	12 Sep 2020 12:36:04

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-10T20:02:53', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5eaff9ce-f173-4665-a383-e2570bc492da' User entered '10 Sep 2020 20:02'	System	12 Sep 2020 12:36:04
	System	12 Sep 2020 12:36:04

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:38:03

US3442113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:38:03

US3442113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:00:53
User entered 'Yes (Y)'		08 Sep 2020 23:13:39

US3442113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:00:56
User entered '8 Sep 2020'		08 Sep 2020 23:13:39

US3442113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:00:57
User entered 'Contact Made (CONTACT MADE)'		08 Sep 2020 23:13:39

US3442113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:00:59
User entered empty.		08 Sep 2020 23:13:39

US3442113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:01:01
User entered 'Yes (Y)'		08 Sep 2020 23:13:45

US3442113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered 'I'	System	08 Sep 2020 23:13:45

US3442113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:13:36
User entered 'Yes (Y)'		15 Sep 2020 19:26:01

US3442113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:13:36
User entered '15 Sep 2020'		15 Sep 2020 19:26:01

US3442113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:13:36
User entered 'Contact Made (CONTACT MADE)'		15 Sep 2020 19:26:01

US3442113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:13:36
User entered empty.		15 Sep 2020 19:26:01

US3442113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:12:29
User entered 'Yes (Y)'		15 Sep 2020 19:26:27

US3442113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered 'I'	System	15 Sep 2020 19:26:27

US3442113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:53:39
User entered 'Yes (Y)'		22 Sep 2020 20:03:53

US3442113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:53:39
User entered '22 Sep 2020'		22 Sep 2020 20:03:53

US3442113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:53:39
User entered 'Contact Made (CONTACT MADE)'		22 Sep 2020 20:03:53

US3442113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:53:39
User entered empty.		22 Sep 2020 20:03:53

US3442113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:29:04
User entered 'Yes (Y)'		22 Sep 2020 20:04:08

US3442113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered 'I'	System	22 Sep 2020 20:04:08

US3442113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:54:38
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:26:20

US3442113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:54:38
User entered '29 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:26:20

US3442113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:54:38
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:26:20

US3442113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'VISIT2'	System	29 Sep 2020 16:26:20

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:56:43
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:56:44
User entered '29 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:56:49
User entered '10:59'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '29 Sep 2020 10:59'	System	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:57:00
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		01 Oct 2020 06:09:30
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'confirmed' (Site from System).	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:28:10
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	29 Sep 2020 16:27:49
User entered '96.7' F	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:57:07
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:57:11
User entered empty.	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:57:18
User entered '50'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'bpm'	System	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:57:29
User entered '12'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'breaths/min'	System	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:57:32
User entered '128'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'mmHg'	System	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:57:33
User entered '74'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'mmHg'	System	29 Sep 2020 16:27:49

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User accepted default value 'Post-Dose (POSTDOSE)'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:09
User entered 'Yes (Y)'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:10
User entered '29 Sep 2020'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:13
User entered '12:10'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '29 Sep 2020 12:10'	System	29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:15
User entered '98.5' F		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:19
User entered 'Oral (Oral)'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:25
User entered empty.		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:28
User entered '47'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'bpm'	System	29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:31
User entered '12'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'breaths/min'	System	29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:35
User entered '128'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'mmHg'	System	29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:58:37
User entered '73'		29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'mmHg'	System	29 Sep 2020 17:15:04

US3442113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:00:32
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:26:27

US3442113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:00:34
User entered '29 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:26:27

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:00:38
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:44:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 16:44:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:44:23
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:29:45
User entered empty.	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:00:40
User entered empty.	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:00:43
User entered empty.	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 16:44:23
User entered empty.	System	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:00:45
User entered '29 Sep 2020' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:44:23
User entered empty.	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:00:47
User entered '11:39' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:44:23
User entered empty.	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '29 Sep 2020 11:39'	System	29 Sep 2020 16:44:23
User entered empty.	System	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:00:52
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:44:23
User entered empty.	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		06 Oct 2020 21:00:56
User entered 'ONCE'	System	29 Sep 2020 16:44:23
User entered empty.	System	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 16:44:23
User entered empty.	System	29 Sep 2020 16:29:45

US3442113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:01:04
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:26:53

US3442113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:01:04
User entered '29 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:26:53

US3442113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:01:04
User entered '11:05'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:26:53

US3442113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '29 Sep 2020 11:05'	System	29 Sep 2020 16:26:53

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:43:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:01:18
User entered '29 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:01:23
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:01:25
User entered '11:10'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '29 Sep 2020 11:10'	System	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		08 Apr 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		08 Apr 2021 05:10:09
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered empty.	System	29 Sep 2020 16:27:05

US3442113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:01:28
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	29 Sep 2020 16:27:11

US3442113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '1'	System	29 Sep 2020 16:27:11

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:11:18', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7a80da38-bc21-41b1-97d7-496cb3a24e6c' User entered 'Yes (Y)'	System	29 Sep 2020 17:11:44
	System	29 Sep 2020 17:11:44

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:11:26', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7a80da38-bc21-41b1-97d7-496cb3a24e6c' User entered '98.5'	System	29 Sep 2020 17:11:44
	System	29 Sep 2020 17:11:44

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:11:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7a80da38-bc21-41b1-97d7-496cb3a24e6c' User entered 'No (N)'	System	29 Sep 2020 17:11:44
	System	29 Sep 2020 17:11:44

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:11:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7a80da38-bc21-41b1-97d7-496cb3a24e6c' User entered '29 Sep 2020 12:11'	System	29 Sep 2020 17:11:44
	System	29 Sep 2020 17:11:44

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 14:29'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:08:06', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7bb2fe19-7dee-4cf8-89cb-aa536d5eb907'	System	30 Sep 2020 01:08:26
User entered 'Yes (Y)'	System	30 Sep 2020 01:08:26

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:08:14', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7bb2fe19-7dee-4cf8-89cb-aa536d5eb907'	System	30 Sep 2020 01:08:26
User entered '97.2'	System	30 Sep 2020 01:08:26

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:08:19', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7bb2fe19-7dee-4cf8-89cb-aa536d5eb907'	System	30 Sep 2020 01:08:26
User entered 'No (N)'	System	30 Sep 2020 01:08:26

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:08:23', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7bb2fe19-7dee-4cf8-89cb-aa536d5eb907'	System	30 Sep 2020 01:08:26
User entered '29 Sep 2020 20:08'	System	30 Sep 2020 01:08:26

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 15:24'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 2'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:28:02', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5063e8bb-1844-49de-a558-59f7fb781486' User entered 'Yes (Y)'	System	01 Oct 2020 00:28:23
	System	01 Oct 2020 00:28:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:28:10', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5063e8bb-1844-49de-a558-59f7fb781486' User entered '99.1'	System	01 Oct 2020 00:28:23
	System	01 Oct 2020 00:28:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:28:15', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5063e8bb-1844-49de-a558-59f7fb781486'	System	01 Oct 2020 00:28:23
User entered 'No (N)'	System	01 Oct 2020 00:28:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:28:20', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '5063e8bb-1844-49de-a558-59f7fb781486'	System	01 Oct 2020 00:28:23
User entered '30 Sep 2020 19:28'	System	01 Oct 2020 00:28:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 3'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:34:14', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1d8456c0-0361-4558-920c-f38055c0698f' User entered 'Yes (Y)'	System	02 Oct 2020 00:34:40
	System	02 Oct 2020 00:34:40

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:34:25', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1d8456c0-0361-4558-920c-f38055c0698f' User entered '97.2'	System	02 Oct 2020 00:34:40
	System	02 Oct 2020 00:34:40

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:34:30', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1d8456c0-0361-4558-920c-f38055c0698f' User entered 'No (N)'	System	02 Oct 2020 00:34:40
	System	02 Oct 2020 00:34:40

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:34:37', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1d8456c0-0361-4558-920c-f38055c0698f' User entered '01 Oct 2020 19:34'	System	02 Oct 2020 00:34:40
	System	02 Oct 2020 00:34:40

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 4'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:03:52', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0af5db5b-69c5-4283-bf41-f504b27090bb' User entered 'Yes (Y)'	System	03 Oct 2020 00:04:08
	System	03 Oct 2020 00:04:08

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:03:59', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0af5db5b-69c5-4283-bf41-f504b27090bb' User entered '97.2'	System	03 Oct 2020 00:04:08
	System	03 Oct 2020 00:04:08

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:02', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0af5db5b-69c5-4283-bf41-f504b27090bb' User entered 'No (N)'	System	03 Oct 2020 00:04:08
	System	03 Oct 2020 00:04:08

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:06', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0af5db5b-69c5-4283-bf41-f504b27090bb' User entered '02 Oct 2020 19:04'	System	03 Oct 2020 00:04:08
	System	03 Oct 2020 00:04:08

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 5'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:44:32', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd76e3643-377b-4d45-862a-e9b9c6016b26' User entered 'Yes (Y)'	System	03 Oct 2020 23:44:53
	System	03 Oct 2020 23:44:53

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:44:39', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd76e3643-377b-4d45-862a-e9b9c6016b26' User entered '97.2'	System	03 Oct 2020 23:44:53
	System	03 Oct 2020 23:44:53

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:44:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd76e3643-377b-4d45-862a-e9b9c6016b26'	System	03 Oct 2020 23:44:53
User entered 'No (N)'	System	03 Oct 2020 23:44:53

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:44:50', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd76e3643-377b-4d45-862a-e9b9c6016b26'	System	03 Oct 2020 23:44:53
User entered '03 Oct 2020 18:44'	System	03 Oct 2020 23:44:53

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 6'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:44:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c98fb2b9-d3cf-4eea-9556-054a22a2d0c8' User entered 'Yes (Y)'	System	05 Oct 2020 01:52:50
	System	05 Oct 2020 01:52:50

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:44:50', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c98fb2b9-d3cf-4eea-9556-054a22a2d0c8' User entered '97.6'	System	05 Oct 2020 01:52:50
	System	05 Oct 2020 01:52:50

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:52:40', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c98fb2b9-d3cf-4eea-9556-054a22a2d0c8'	System	05 Oct 2020 01:52:50
User entered 'No (N)'	System	05 Oct 2020 01:52:50

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:52:47', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c98fb2b9-d3cf-4eea-9556-054a22a2d0c8' User entered '04 Oct 2020 20:52'	System	05 Oct 2020 01:52:50
	System	05 Oct 2020 01:52:50

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 7'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:32:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f72facb-0418-4697-b4de-540845d80904' User entered 'Yes (Y)'	System	06 Oct 2020 00:32:59
	System	06 Oct 2020 00:32:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:32:38', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f72facb-0418-4697-b4de-540845d80904' User entered '98.1'	System	06 Oct 2020 00:32:59
	System	06 Oct 2020 00:32:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:32:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f72facb-0418-4697-b4de-540845d80904'	System	06 Oct 2020 00:32:59
User entered 'No (N)'	System	06 Oct 2020 00:32:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:32:56', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '6f72facb-0418-4697-b4de-540845d80904'	System	06 Oct 2020 00:32:59
User entered '05 Oct 2020 19:32'	System	06 Oct 2020 00:32:59

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:07', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fb5980c-302b-451d-94ba-71687f5150ef' User entered 'None (1)'	System	29 Sep 2020 17:12:24
	System	29 Sep 2020 17:12:24

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:10', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fb5980c-302b-451d-94ba-71687f5150ef' User entered 'No (N)'	System	29 Sep 2020 17:12:24
	System	29 Sep 2020 17:12:24

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:14', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fb5980c-302b-451d-94ba-71687f5150ef' User entered 'No (N)'	System	29 Sep 2020 17:12:24
	System	29 Sep 2020 17:12:24

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:18', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fb5980c-302b-451d-94ba-71687f5150ef' User entered 'None (1)'	System	29 Sep 2020 17:12:24
	System	29 Sep 2020 17:12:24

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:22', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fb5980c-302b-451d-94ba-71687f5150ef' User entered '29 Sep 2020 12:12'	System	29 Sep 2020 17:12:24
	System	29 Sep 2020 17:12:24

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 14:29'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:09:12', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f639624b-5cb6-4774-8b85-2cef83151a7e' User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 01:13:18
	System	30 Sep 2020 01:13:18

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:09:34', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f639624b-5cb6-4774-8b85-2cef83151a7e' User entered 'No (N)'	System	30 Sep 2020 01:13:18
	System	30 Sep 2020 01:13:18

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:09:39', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f639624b-5cb6-4774-8b85-2cef83151a7e' User entered 'Yes (Y)'	System	30 Sep 2020 01:13:18
	System	30 Sep 2020 01:13:18

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:12:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f639624b-5cb6-4774-8b85-2cef83151a7e' User entered '6'	System	30 Sep 2020 01:13:18
	System	30 Sep 2020 01:13:18

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:12:55', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f639624b-5cb6-4774-8b85-2cef83151a7e' User entered 'None (1)'	System	30 Sep 2020 01:13:18
	System	30 Sep 2020 01:13:18

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:13:16', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f639624b-5cb6-4774-8b85-2cef83151a7e' User entered '29 Sep 2020 20:13'	System	30 Sep 2020 01:13:18
	System	30 Sep 2020 01:13:18

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 15:24'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 2'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:29:23', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f659ab1-ee12-4e32-8504-e6d0f9a8b1d9'	System	01 Oct 2020 00:30:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	01 Oct 2020 00:30:29

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:29:35', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f659ab1-ee12-4e32-8504-e6d0f9a8b1d9' User entered 'No (N)'	System	01 Oct 2020 00:30:29
	System	01 Oct 2020 00:30:29

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:29:40', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f659ab1-ee12-4e32-8504-e6d0f9a8b1d9' User entered 'Yes (Y)'	System	01 Oct 2020 00:30:29
	System	01 Oct 2020 00:30:29

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:29:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f659ab1-ee12-4e32-8504-e6d0f9a8b1d9'	System	01 Oct 2020 00:30:29
User entered '105'	System	01 Oct 2020 00:30:29

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:30:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f659ab1-ee12-4e32-8504-e6d0f9a8b1d9'	System	01 Oct 2020 00:30:29
User entered 'None (1)'	System	01 Oct 2020 00:30:29

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:30:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0f659ab1-ee12-4e32-8504-e6d0f9a8b1d9'	System	01 Oct 2020 00:30:29
User entered '30 Sep 2020 19:30'	System	01 Oct 2020 00:30:29

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 3'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:35:08', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'aba5207c-d463-415f-9f23-2ea7a68ef828'	System	02 Oct 2020 00:39:39
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	02 Oct 2020 00:39:39

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:35:12', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'aba5207c-d463-415f-9f23-2ea7a68ef828'	System	02 Oct 2020 00:39:39
User entered 'Yes (Y)'	System	02 Oct 2020 00:39:39

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:36:45', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'aba5207c-d463-415f-9f23-2ea7a68ef828'	System	02 Oct 2020 00:39:39
User entered '11'	System	02 Oct 2020 00:39:39

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:37:16', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'aba5207c-d463-415f-9f23-2ea7a68ef828'	System	02 Oct 2020 00:39:39
User entered 'Yes (Y)'	System	02 Oct 2020 00:39:39

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:39:12', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'aba5207c-d463-415f-9f23-2ea7a68ef828'	System	02 Oct 2020 00:39:39
User entered '10'	System	02 Oct 2020 00:39:39

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:39:29', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'aba5207c-d463-415f-9f23-2ea7a68ef828'	System	02 Oct 2020 00:39:39
User entered 'None (1)'	System	02 Oct 2020 00:39:39

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:39:36', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'aba5207c-d463-415f-9f23-2ea7a68ef828'	System	02 Oct 2020 00:39:39
User entered '01 Oct 2020 19:39'	System	02 Oct 2020 00:39:39

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 4'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:16', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '80dcef29-5f43-4790-bb20-23df965f0de1' User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 00:04:45
	System	03 Oct 2020 00:04:45

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:19', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '80dcef29-5f43-4790-bb20-23df965f0de1' User entered 'No (N)'	System	03 Oct 2020 00:04:45
	System	03 Oct 2020 00:04:45

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:24', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '80dcef29-5f43-4790-bb20-23df965f0de1' User entered 'Yes (Y)'	System	03 Oct 2020 00:04:45
	System	03 Oct 2020 00:04:45

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:34', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '80dcef29-5f43-4790-bb20-23df965f0de1' User entered '6'	System	03 Oct 2020 00:04:45
	System	03 Oct 2020 00:04:45

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:39', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '80dcef29-5f43-4790-bb20-23df965f0de1'	System	03 Oct 2020 00:04:45
User entered 'None (1)'	System	03 Oct 2020 00:04:45

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:42', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '80dcef29-5f43-4790-bb20-23df965f0de1' User entered '02 Oct 2020 19:04'	System	03 Oct 2020 00:04:45
	System	03 Oct 2020 00:04:45

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 5'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:06', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd32db59f-ec30-4417-8587-d83dbb6c4bd6'	System	03 Oct 2020 23:45:30
User entered 'None (1)'	System	03 Oct 2020 23:45:30

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:12', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd32db59f-ec30-4417-8587-d83dbb6c4bd6'	System	03 Oct 2020 23:45:30
User entered 'No (N)'	System	03 Oct 2020 23:45:30

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:16', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd32db59f-ec30-4417-8587-d83dbb6c4bd6' User entered 'No (N)'	System	03 Oct 2020 23:45:30
	System	03 Oct 2020 23:45:30

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:24', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd32db59f-ec30-4417-8587-d83dbb6c4bd6'	System	03 Oct 2020 23:45:30
User entered 'None (1)'	System	03 Oct 2020 23:45:30

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd32db59f-ec30-4417-8587-d83dbb6c4bd6' User entered '03 Oct 2020 18:45'	System	03 Oct 2020 23:45:30
	System	03 Oct 2020 23:45:30

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 6'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:53:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e3ba0601-aca1-42f7-ad90-4256622ace4b' User entered 'None (1)'	System	05 Oct 2020 01:54:08
	System	05 Oct 2020 01:54:08

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:53:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e3ba0601-aca1-42f7-ad90-4256622ace4b' User entered 'No (N)'	System	05 Oct 2020 01:54:08
	System	05 Oct 2020 01:54:08

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:53:52', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e3ba0601-aca1-42f7-ad90-4256622ace4b' User entered 'No (N)'	System	05 Oct 2020 01:54:08
	System	05 Oct 2020 01:54:08

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:01', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e3ba0601-aca1-42f7-ad90-4256622ace4b' User entered 'None (1)'	System	05 Oct 2020 01:54:08
	System	05 Oct 2020 01:54:08

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:05', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e3ba0601-aca1-42f7-ad90-4256622ace4b' User entered '04 Oct 2020 20:54'	System	05 Oct 2020 01:54:08
	System	05 Oct 2020 01:54:08

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 7'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:04', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '87d28fc0-0b69-4814-8d81-3600fd112975'	System	06 Oct 2020 00:33:23
User entered 'None (1)'	System	06 Oct 2020 00:33:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:07', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '87d28fc0-0b69-4814-8d81-3600fd112975'	System	06 Oct 2020 00:33:23
User entered 'No (N)'	System	06 Oct 2020 00:33:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:10', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '87d28fc0-0b69-4814-8d81-3600fd112975'	System	06 Oct 2020 00:33:23
User entered 'No (N)'	System	06 Oct 2020 00:33:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:17', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '87d28fc0-0b69-4814-8d81-3600fd112975' User entered 'None (1)'	System	06 Oct 2020 00:33:23
	System	06 Oct 2020 00:33:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:20', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '87d28fc0-0b69-4814-8d81-3600fd112975' User entered '05 Oct 2020 19:33'	System	06 Oct 2020 00:33:23
	System	06 Oct 2020 00:33:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:26', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f79661bc-9b20-41e3-8fd2-bf826cfea25f' User entered 'None (0)'	System	29 Sep 2020 17:12:51
	System	29 Sep 2020 17:12:51

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:29', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f79661bc-9b20-41e3-8fd2-bf826cfea25f' User entered 'None (0)'	System	29 Sep 2020 17:12:51
	System	29 Sep 2020 17:12:51

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:32', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f79661bc-9b20-41e3-8fd2-bf826cfea25f' User entered 'None (0)'	System	29 Sep 2020 17:12:51
	System	29 Sep 2020 17:12:51

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:35', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f79661bc-9b20-41e3-8fd2-bf826cfea25f' User entered 'None (0)'	System	29 Sep 2020 17:12:51
	System	29 Sep 2020 17:12:51

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:37', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f79661bc-9b20-41e3-8fd2-bf826cfea25f' User entered 'None (0)'	System	29 Sep 2020 17:12:51
	System	29 Sep 2020 17:12:51

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:39', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f79661bc-9b20-41e3-8fd2-bf826cfea25f' User entered 'None (0)'	System	29 Sep 2020 17:12:51
	System	29 Sep 2020 17:12:51

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:45', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f79661bc-9b20-41e3-8fd2-bf826cfea25f' User entered 'No (N)'	System	29 Sep 2020 17:12:51
	System	29 Sep 2020 17:12:51

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T12:12:49', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f79661bc-9b20-41e3-8fd2-bf826cfea25f' User entered '29 Sep 2020 12:12'	System	29 Sep 2020 17:12:51
	System	29 Sep 2020 17:12:51

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 14:29'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:13:22', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2062da26-2a5b-4de7-b0b1-857cfa94861a' User entered 'None (0)'	System	30 Sep 2020 01:14:11
	System	30 Sep 2020 01:14:11

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:13:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2062da26-2a5b-4de7-b0b1-857cfa94861a' User entered 'None (0)'	System	30 Sep 2020 01:14:11
	System	30 Sep 2020 01:14:11

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:13:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2062da26-2a5b-4de7-b0b1-857cfa94861a' User entered 'None (0)'	System	30 Sep 2020 01:14:11
	System	30 Sep 2020 01:14:11

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:13:35', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2062da26-2a5b-4de7-b0b1-857cfa94861a' User entered 'None (0)'	System	30 Sep 2020 01:14:11
	System	30 Sep 2020 01:14:11

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:13:55', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2062da26-2a5b-4de7-b0b1-857cfa94861a' User entered 'None (0)'	System	30 Sep 2020 01:14:11
	System	30 Sep 2020 01:14:11

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:13:58', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2062da26-2a5b-4de7-b0b1-857cfa94861a' User entered 'None (0)'	System	30 Sep 2020 01:14:11
	System	30 Sep 2020 01:14:11

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:14:05', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2062da26-2a5b-4de7-b0b1-857cfa94861a' User entered 'No (N)'	System	30 Sep 2020 01:14:11
	System	30 Sep 2020 01:14:11

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-29T20:14:08', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2062da26-2a5b-4de7-b0b1-857cfa94861a' User entered '29 Sep 2020 20:14'	System	30 Sep 2020 01:14:11
	System	30 Sep 2020 01:14:11

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '29 Sep 2020 15:24'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 2'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:30:37', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd9fb8261-3e48-4c78-9d47-68c526f17f76'	System	01 Oct 2020 00:32:12
User entered 'None (0)'	System	01 Oct 2020 00:32:12

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:31:20', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd9fb8261-3e48-4c78-9d47-68c526f17f76'	System	01 Oct 2020 00:32:12
User entered 'Significant; prevents daily activity (3)'	System	01 Oct 2020 00:32:12

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:31:29', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd9fb8261-3e48-4c78-9d47-68c526f17f76'	System	01 Oct 2020 00:32:12
User entered 'Some interference with activity (2)'	System	01 Oct 2020 00:32:12

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:31:38', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd9fb8261-3e48-4c78-9d47-68c526f17f76'	System	01 Oct 2020 00:32:12
User entered 'Some interference with activity (2)'	System	01 Oct 2020 00:32:12

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:31:54', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd9fb8261-3e48-4c78-9d47-68c526f17f76'	System	01 Oct 2020 00:32:12
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Oct 2020 00:32:12

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:31:59', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd9fb8261-3e48-4c78-9d47-68c526f17f76'	System	01 Oct 2020 00:32:12
User entered 'No interference with activity (1)'	System	01 Oct 2020 00:32:12

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:32:04', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd9fb8261-3e48-4c78-9d47-68c526f17f76'	System	01 Oct 2020 00:32:12
User entered 'No (N)'	System	01 Oct 2020 00:32:12

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-09-30T19:32:09', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd9fb8261-3e48-4c78-9d47-68c526f17f76'	System	01 Oct 2020 00:32:12
User entered '30 Sep 2020 19:32'	System	01 Oct 2020 00:32:12

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 3'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:39:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fde8e57-3304-4b75-9219-57145f89a855'	System	02 Oct 2020 00:40:36
User entered 'None (0)'	System	02 Oct 2020 00:40:36

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:39:53', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fde8e57-3304-4b75-9219-57145f89a855'	System	02 Oct 2020 00:40:36
User entered 'None (0)'	System	02 Oct 2020 00:40:36

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:40:03', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fde8e57-3304-4b75-9219-57145f89a855'	System	02 Oct 2020 00:40:36
User entered 'None (0)'	System	02 Oct 2020 00:40:36

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:40:10', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fde8e57-3304-4b75-9219-57145f89a855'	System	02 Oct 2020 00:40:36
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:40:36

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:40:13', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fde8e57-3304-4b75-9219-57145f89a855'	System	02 Oct 2020 00:40:36
User entered 'None (0)'	System	02 Oct 2020 00:40:36

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:40:25', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fde8e57-3304-4b75-9219-57145f89a855'	System	02 Oct 2020 00:40:36
User entered 'None (0)'	System	02 Oct 2020 00:40:36

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:40:30', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fde8e57-3304-4b75-9219-57145f89a855'	System	02 Oct 2020 00:40:36
User entered 'No (N)'	System	02 Oct 2020 00:40:36

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-01T19:40:33', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fde8e57-3304-4b75-9219-57145f89a855'	System	02 Oct 2020 00:40:36
User entered '01 Oct 2020 19:40'	System	02 Oct 2020 00:40:36

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 4'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:47', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4e34948c-6543-4499-beb6-aa5fc85a0b7a' User entered 'None (0)'	System	03 Oct 2020 00:05:23
	System	03 Oct 2020 00:05:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:54', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4e34948c-6543-4499-beb6-aa5fc85a0b7a' User entered 'Some interference with activity (2)'	System	03 Oct 2020 00:05:23
	System	03 Oct 2020 00:05:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:04:59', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4e34948c-6543-4499-beb6-aa5fc85a0b7a' User entered 'None (0)'	System	03 Oct 2020 00:05:23
	System	03 Oct 2020 00:05:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:05:07', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4e34948c-6543-4499-beb6-aa5fc85a0b7a' User entered 'None (0)'	System	03 Oct 2020 00:05:23
	System	03 Oct 2020 00:05:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:05:10', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4e34948c-6543-4499-beb6-aa5fc85a0b7a' User entered 'None (0)'	System	03 Oct 2020 00:05:23
	System	03 Oct 2020 00:05:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:05:13', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4e34948c-6543-4499-beb6-aa5fc85a0b7a' User entered 'None (0)'	System	03 Oct 2020 00:05:23
	System	03 Oct 2020 00:05:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:05:17', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4e34948c-6543-4499-beb6-aa5fc85a0b7a' User entered 'No (N)'	System	03 Oct 2020 00:05:23
	System	03 Oct 2020 00:05:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-02T19:05:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4e34948c-6543-4499-beb6-aa5fc85a0b7a' User entered '02 Oct 2020 19:05'	System	03 Oct 2020 00:05:23
	System	03 Oct 2020 00:05:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 5'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:33', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '13922e76-1b88-4968-b7ac-21d2c53c1895' User entered 'None (0)'	System	03 Oct 2020 23:46:03
	System	03 Oct 2020 23:46:03

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:37', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '13922e76-1b88-4968-b7ac-21d2c53c1895' User entered 'None (0)'	System	03 Oct 2020 23:46:03
	System	03 Oct 2020 23:46:03

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:40', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '13922e76-1b88-4968-b7ac-21d2c53c1895' User entered 'None (0)'	System	03 Oct 2020 23:46:03
	System	03 Oct 2020 23:46:03

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '13922e76-1b88-4968-b7ac-21d2c53c1895' User entered 'None (0)'	System	03 Oct 2020 23:46:03
	System	03 Oct 2020 23:46:03

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:47', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '13922e76-1b88-4968-b7ac-21d2c53c1895' User entered 'None (0)'	System	03 Oct 2020 23:46:03
	System	03 Oct 2020 23:46:03

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:51', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '13922e76-1b88-4968-b7ac-21d2c53c1895' User entered 'None (0)'	System	03 Oct 2020 23:46:03
	System	03 Oct 2020 23:46:03

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:55', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '13922e76-1b88-4968-b7ac-21d2c53c1895'	System	03 Oct 2020 23:46:03
User entered 'No (N)'	System	03 Oct 2020 23:46:03

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-03T18:45:58', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '13922e76-1b88-4968-b7ac-21d2c53c1895'	System	03 Oct 2020 23:46:03
User entered '03 Oct 2020 18:45'	System	03 Oct 2020 23:46:03

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 6'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:19', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fa6924db-37f1-4b28-bf10-5dd9219dbecf' User entered 'None (0)'	System	05 Oct 2020 01:54:43
	System	05 Oct 2020 01:54:43

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:25', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fa6924db-37f1-4b28-bf10-5dd9219dbecf' User entered 'None (0)'	System	05 Oct 2020 01:54:43
	System	05 Oct 2020 01:54:43

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fa6924db-37f1-4b28-bf10-5dd9219dbecf' User entered 'None (0)'	System	05 Oct 2020 01:54:43
	System	05 Oct 2020 01:54:43

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:29', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fa6924db-37f1-4b28-bf10-5dd9219dbecf' User entered 'None (0)'	System	05 Oct 2020 01:54:43
	System	05 Oct 2020 01:54:43

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fa6924db-37f1-4b28-bf10-5dd9219dbecf' User entered 'None (0)'	System	05 Oct 2020 01:54:43
	System	05 Oct 2020 01:54:43

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:33', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fa6924db-37f1-4b28-bf10-5dd9219dbecf' User entered 'None (0)'	System	05 Oct 2020 01:54:43
	System	05 Oct 2020 01:54:43

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:38', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fa6924db-37f1-4b28-bf10-5dd9219dbecf' User entered 'No (N)'	System	05 Oct 2020 01:54:43
	System	05 Oct 2020 01:54:43

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-04T20:54:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fa6924db-37f1-4b28-bf10-5dd9219dbecf' User entered '04 Oct 2020 20:54'	System	05 Oct 2020 01:54:43
	System	05 Oct 2020 01:54:43

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	29 Sep 2020 16:44:23
User entered 'Day 7'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:30', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '27c4b1e9-f3ef-4ff2-9262-f1223a4d4b70'	System	06 Oct 2020 00:34:04
User entered 'None (0)'	System	06 Oct 2020 00:34:04

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:36', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '27c4b1e9-f3ef-4ff2-9262-f1223a4d4b70'	System	06 Oct 2020 00:34:04
User entered 'None (0)'	System	06 Oct 2020 00:34:04

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:39', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '27c4b1e9-f3ef-4ff2-9262-f1223a4d4b70'	System	06 Oct 2020 00:34:04
User entered 'None (0)'	System	06 Oct 2020 00:34:04

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '27c4b1e9-f3ef-4ff2-9262-f1223a4d4b70' User entered 'None (0)'	System	06 Oct 2020 00:34:04
	System	06 Oct 2020 00:34:04

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:46', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '27c4b1e9-f3ef-4ff2-9262-f1223a4d4b70'	System	06 Oct 2020 00:34:04
User entered 'None (0)'	System	06 Oct 2020 00:34:04

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:49', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '27c4b1e9-f3ef-4ff2-9262-f1223a4d4b70' User entered 'None (0)'	System	06 Oct 2020 00:34:04
	System	06 Oct 2020 00:34:04

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:33:55', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '27c4b1e9-f3ef-4ff2-9262-f1223a4d4b70'	System	06 Oct 2020 00:34:04
User entered 'No (N)'	System	06 Oct 2020 00:34:04

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-10-05T19:34:01', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '27c4b1e9-f3ef-4ff2-9262-f1223a4d4b70' User entered '05 Oct 2020 19:34'	System	06 Oct 2020 00:34:04
	System	06 Oct 2020 00:34:04

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 16:44:23

US3442113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 16:44:23

US3442113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:03
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:45:18

US3442113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:03
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '6 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 14:45:18

US3442113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:03
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:45:18

US3442113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:03
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:45:18

US3442113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:06
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:45:24

US3442113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered 'I'	System	08 Oct 2020 14:45:24

US3442113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) Tisha Davis (b) (4) (b) (4)	13 Oct 2020 22:47:00

US3442113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '13 Oct 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	13 Oct 2020 22:47:00

US3442113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tisha Davis (b) (4) (b) (4)	13 Oct 2020 22:47:00

US3442113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	13 Oct 2020 22:47:00

US3442113

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:30
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) Tisha Davis (b) (4) (b) (4)	13 Oct 2020 22:47:05

US3442113

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered 'I'	System	13 Oct 2020 22:47:05

US3442113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:29:12

US3442113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:29:12

US3442113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 16:29:12

US3442113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:30:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:29:12

US3442113

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:31:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:29:20

US3442113

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered 'I'	System	20 Oct 2020 16:29:20

US3442113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:49:45

US3442113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:49:45

US3442113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Oct 2020 17:49:45

US3442113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered 'VISIT3'	System	26 Oct 2020 17:49:45

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered empty.	System	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered empty.	System	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered empty.	System	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered empty.	System	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered empty.	System	26 Oct 2020 17:50:23

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55

US3442113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55

US3442113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:35
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:17

US3442113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:35
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 17:50:17

US3442113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:24
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:05

US3442113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:24
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:05

US3442113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:31:24
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '12:16'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:05

US3442113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '26 Oct 2020 12:16'	System	26 Oct 2020 17:50:05

US3442113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
DataPoint Verified.		11 Mar 2021 20:32:07
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:50:10

US3442113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:55
User entered '1'	System	26 Oct 2020 17:50:10

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 64'	System	01 Sep 2020 19:46:23

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-02T12:41:06', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fea0c9b-4c24-4991-b2ba-f5d224152e6a'	System	02 Nov 2020 18:42:15
User entered 'No (N)'	System	02 Nov 2020 18:42:15

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-02T12:41:58', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fea0c9b-4c24-4991-b2ba-f5d224152e6a'	System	02 Nov 2020 18:42:15
User entered 'No (N)'	System	02 Nov 2020 18:42:15

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-02T12:42:11', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8fea0c9b-4c24-4991-b2ba-f5d224152e6a' User entered '02 Nov 2020 12:42:11'	System	02 Nov 2020 18:42:15
	System	02 Nov 2020 18:42:15

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 19:46:23

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 71'	System	01 Sep 2020 19:46:23

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-08T07:14:08', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6fceb8-534d-4863-a1d3-a88ff49f527a' User entered 'No (N)'	System	08 Nov 2020 13:14:33
	System	08 Nov 2020 13:14:33

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-08T07:14:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6fceb8-534d-4863-a1d3-a88ff49f527a' User entered 'No (N)'	System	08 Nov 2020 13:14:33
	System	08 Nov 2020 13:14:33

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-08T07:14:31', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd6fceb8-534d-4863-a1d3-a88ff49f527a' User entered '08 Nov 2020 07:14:31'	System	08 Nov 2020 13:14:33
	System	08 Nov 2020 13:14:33

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 19:46:23

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered 'Day 78'	System	01 Sep 2020 19:46:23

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-15T22:22:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f47e783-6a1d-42d8-bfa7-5c9a801e77ac'	System	16 Nov 2020 04:23:40
User entered 'No (N)'	System	16 Nov 2020 04:23:40

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-15T22:23:23', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f47e783-6a1d-42d8-bfa7-5c9a801e77ac'	System	16 Nov 2020 04:23:40
User entered 'No (N)'	System	16 Nov 2020 04:23:40

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-15T22:23:34', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f47e783-6a1d-42d8-bfa7-5c9a801e77ac' User entered '15 Nov 2020 22:23:34'	System	16 Nov 2020 04:23:40
	System	16 Nov 2020 04:23:40

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 19:46:23

US3442113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:14:10
Data entry locked.	System	01 Sep 2020 19:46:23
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 19:46:23

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-19T21:25:23', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c93f23eb-fb05-4e58-94be-ca29ecec4f2'	System	20 Nov 2020 03:25:51
User entered 'No (N)'	System	20 Nov 2020 03:25:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-19T21:25:39', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c93f23eb-fb05-4e58-94be-ca29ecec4f2'	System	20 Nov 2020 03:25:51
User entered 'No (N)'	System	20 Nov 2020 03:25:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-19T21:25:47', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'c93f23eb-fb05-4e58-94be-ca29eceedc4f2' User entered '19 Nov 2020 21:25:47'	System	20 Nov 2020 03:25:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-28T17:37:27', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '59542ef4-4d2f-4af5-800e-867cad22742f' User entered 'No (N)'	System	28 Nov 2020 23:37:53

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-28T17:37:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '59542ef4-4d2f-4af5-800e-867cad22742f' User entered 'No (N)'	System	28 Nov 2020 23:37:53

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E0987A9B-DC66-44F9-88ED-3CF9F960FD49)', Time: '2020-11-28T17:37:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '59542ef4-4d2f-4af5-800e-867cad22742f' User entered '28 Nov 2020 17:37:48'	System	28 Nov 2020 23:37:53
	System	28 Nov 2020 23:37:53

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-07T09:50:38', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e7531539-9021-45d9-979c-36d36496b2ef' User entered 'No (N)'	System	07 Dec 2020 15:50:50
	System	07 Dec 2020 15:50:50

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-07T09:50:42', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e7531539-9021-45d9-979c-36d36496b2ef' User entered 'No (N)'	System	07 Dec 2020 15:50:50
	System	07 Dec 2020 15:50:50

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-07T09:50:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e7531539-9021-45d9-979c-36d36496b2ef' User entered '07 Dec 2020 09:50:48'	System	07 Dec 2020 15:50:50
	System	07 Dec 2020 15:50:50

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-10T09:40:34', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '422bcbd5-9c21-4baf-ab5e-eeca00dd2069' User entered 'No (N)'	System	10 Dec 2020 15:40:51
	System	10 Dec 2020 15:40:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-10T09:40:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '422bcbd5-9c21-4baf-ab5e-eeca00dd2069' User entered 'No (N)'	System	10 Dec 2020 15:40:51
	System	10 Dec 2020 15:40:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-10T09:40:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '422bcbd5-9c21-4baf-ab5e-eeca00dd2069' User entered '10 Dec 2020 09:40:48'	System	10 Dec 2020 15:40:51
	System	10 Dec 2020 15:40:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-17T16:14:38', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f8a5ce8-b955-4fd2-851f-a671d20cb95d' User entered 'No (N)'	System	17 Dec 2020 22:14:57
	System	17 Dec 2020 22:14:57

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-17T16:14:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f8a5ce8-b955-4fd2-851f-a671d20cb95d'	System	17 Dec 2020 22:14:57
User entered 'No (N)'	System	17 Dec 2020 22:14:57

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-17T16:14:53', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '1f8a5ce8-b955-4fd2-851f-a671d20cb95d' User entered '17 Dec 2020 16:14:53'	System	17 Dec 2020 22:14:57
	System	17 Dec 2020 22:14:57

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-24T07:10:24', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd791a564-5191-4919-b813-41653486a78a'	System	24 Dec 2020 13:11:14
User entered 'No (N)'	System	24 Dec 2020 13:11:14

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-24T07:10:34', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd791a564-5191-4919-b813-41653486a78a'	System	24 Dec 2020 13:11:14
User entered 'No (N)'	System	24 Dec 2020 13:11:14

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-24T07:11:10', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'd791a564-5191-4919-b813-41653486a78a' User entered '24 Dec 2020 07:11:10'	System	24 Dec 2020 13:11:14
	System	24 Dec 2020 13:11:14

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-31T08:27:21', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fd0f6f5d-4689-4646-addb-2543016d155a' User entered 'No (N)'	System	31 Dec 2020 14:27:35
	System	31 Dec 2020 14:27:35

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-31T08:27:28', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fd0f6f5d-4689-4646-addb-2543016d155a' User entered 'No (N)'	System	31 Dec 2020 14:27:35
	System	31 Dec 2020 14:27:35

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2020-12-31T08:27:33', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'fd0f6f5d-4689-4646-addb-2543016d155a' User entered '31 Dec 2020 08:27:33'	System	31 Dec 2020 14:27:35
	System	31 Dec 2020 14:27:35

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-09T06:04:53', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e6401284-8149-4027-be19-0a35aad2a9a' User entered 'No (N)'	System	09 Jan 2021 12:05:02
	System	09 Jan 2021 12:05:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-09T06:04:57', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e6401284-8149-4027-be19-0a35aad2a9a' User entered 'No (N)'	System	09 Jan 2021 12:05:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-09T06:05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'e6401284-8149-4027-be19-0a35aad2a9a' User entered '09 Jan 2021 06:05:00'	System	09 Jan 2021 12:05:02
	System	09 Jan 2021 12:05:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-14T16:00:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2bc59efb-998e-423e-bd6a-d7b1a55b50d3'	System	14 Jan 2021 22:00:55
User entered 'No (N)'	System	14 Jan 2021 22:00:55

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-14T16:00:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2bc59efb-998e-423e-bd6a-d7b1a55b50d3'	System	14 Jan 2021 22:00:55
User entered 'No (N)'	System	14 Jan 2021 22:00:55

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-14T16:00:52', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '2bc59efb-998e-423e-bd6a-d7b1a55b50d3' User entered '14 Jan 2021 16:00:52'	System	14 Jan 2021 22:00:55
	System	14 Jan 2021 22:00:55

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-21T08:45:45', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7aa8592c-3bae-4ca6-ac4e-b791e8514fbc' User entered 'No (N)'	System	21 Jan 2021 14:45:56

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-21T08:45:48', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7aa8592c-3bae-4ca6-ac4e-b791e8514fbc' User entered 'No (N)'	System	21 Jan 2021 14:45:56
	System	21 Jan 2021 14:45:56

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-21T08:45:53', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '7aa8592c-3bae-4ca6-ac4e-b791e8514fbc' User entered '21 Jan 2021 08:45:53'	System	21 Jan 2021 14:45:56
	System	21 Jan 2021 14:45:56

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-29T08:07:34', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'baedb649-407e-47d8-9ccd-43261e7830fc' User entered 'No (N)'	System	29 Jan 2021 14:07:52
	System	29 Jan 2021 14:07:52

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-29T08:07:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'baedb649-407e-47d8-9ccd-43261e7830fc' User entered 'No (N)'	System	29 Jan 2021 14:07:52

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-01-29T08:07:47', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'baedb649-407e-47d8-9ccd-43261e7830fc' User entered '29 Jan 2021 08:07:47'	System	29 Jan 2021 14:07:52
	System	29 Jan 2021 14:07:52

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-04T19:44:07', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f504fae6-3220-4748-b270-8cf1dcDCF27a' User entered 'No (N)'	System	05 Feb 2021 01:44:27

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-04T19:44:19', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f504fae6-3220-4748-b270-8cf1dcdf27a' User entered 'No (N)'	System	05 Feb 2021 01:44:27

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-04T19:44:24', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f504fae6-3220-4748-b270-8cf1dcDCF27a' User entered '04 Feb 2021 19:44:24'	System	05 Feb 2021 01:44:27

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-11T06:53:33', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '33683817-3dcf-4c23-a477-a751f5c4fc46'	System	11 Feb 2021 12:53:51
User entered 'No (N)'	System	11 Feb 2021 12:53:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-11T06:53:43', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '33683817-3dcf-4c23-a477-a751f5c4fc46'	System	11 Feb 2021 12:53:51
User entered 'No (N)'	System	11 Feb 2021 12:53:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-11T06:53:49', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '33683817-3dcf-4c23-a477-a751f5c4fc46'	System	11 Feb 2021 12:53:51
User entered '11 Feb 2021 06:53:49'	System	11 Feb 2021 12:53:51

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-18T10:42:41', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b0cb5e54-54b3-46d1-a6c0-f95c28581ed9' User entered 'No (N)'	System	18 Feb 2021 16:42:52
	System	18 Feb 2021 16:42:52

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-18T10:42:44', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b0cb5e54-54b3-46d1-a6c0-f95c28581ed9' User entered 'No (N)'	System	18 Feb 2021 16:42:52
	System	18 Feb 2021 16:42:52

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-18T10:42:49', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'b0cb5e54-54b3-46d1-a6c0-f95c28581ed9' User entered '18 Feb 2021 10:42:49'	System	18 Feb 2021 16:42:52
	System	18 Feb 2021 16:42:52

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-28T17:59:24-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f91a4bae-610e-4b97-9faa-8bdc6a45a3a8'	System	28 Feb 2021 23:59:33
User entered 'No (N)'	System	28 Feb 2021 23:59:33

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-28T17:59:26-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f91a4bae-610e-4b97-9faa-8bdc6a45a3a8'	System	28 Feb 2021 23:59:33
User entered 'No (N)'	System	28 Feb 2021 23:59:33

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-28T17:59:29-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f91a4bae-610e-4b97-9faa-8bdc6a45a3a8'	System	28 Feb 2021 23:59:33
User entered '28 Feb 2021 23:59:29'	System	28 Feb 2021 23:59:33

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-06T12:00:49-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '060e55a2-7737-43ac-84b6-ca50633154a1'	System	06 Mar 2021 18:01:28
User entered 'No (N)'	System	06 Mar 2021 18:01:28

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-06T12:00:52-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '060e55a2-7737-43ac-84b6-ca50633154a1'	System	06 Mar 2021 18:01:28
User entered 'No (N)'	System	06 Mar 2021 18:01:28

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-06T12:00:56-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '060e55a2-7737-43ac-84b6-ca50633154a1' User entered '06 Mar 2021 12:00:56'	System	06 Mar 2021 18:01:28
	System	06 Mar 2021 18:01:28

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-11T07:14:38-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f8dc94c6-7a2a-4176-99a2-f80351c1b92e'	System	11 Mar 2021 13:14:54
User entered 'No (N)'	System	11 Mar 2021 13:14:54

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-11T07:14:41-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f8dc94c6-7a2a-4176-99a2-f80351c1b92e'	System	11 Mar 2021 13:14:54
User entered 'No (N)'	System	11 Mar 2021 13:14:54

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-11T07:14:48-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'f8dc94c6-7a2a-4176-99a2-f80351c1b92e' User entered '11 Mar 2021 07:14:48'	System	11 Mar 2021 13:14:54
	System	11 Mar 2021 13:14:54

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-19T08:25:22-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4415d288-8757-46a1-b788-b1c36150ea82'	System	19 Mar 2021 13:25:36
User entered 'No (N)'	System	19 Mar 2021 13:25:36

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-19T08:25:26-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4415d288-8757-46a1-b788-b1c36150ea82'	System	19 Mar 2021 13:25:36
User entered 'No (N)'	System	19 Mar 2021 13:25:36

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-19T08:25:33-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4415d288-8757-46a1-b788-b1c36150ea82'	System	19 Mar 2021 13:25:36
User entered '19 Mar 2021 08:25:33'	System	19 Mar 2021 13:25:36

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-25T07:03:52-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '384ac510-24e1-4698-b8ee-769d33b1360e' User entered 'No (N)'	System	25 Mar 2021 12:04:14
	System	25 Mar 2021 12:04:14

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-25T07:04:01-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '384ac510-24e1-4698-b8ee-769d33b1360e' User entered 'No (N)'	System	25 Mar 2021 12:04:14
	System	25 Mar 2021 12:04:14

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-03-25T07:04:09-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '384ac510-24e1-4698-b8ee-769d33b1360e' User entered '25 Mar 2021 07:04:09'	System	25 Mar 2021 12:04:14
	System	25 Mar 2021 12:04:14

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-02T06:15:41-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '70af4e9e-0ad1-433c-b378-dd395d83c316'	System	04 Apr 2021 12:59:00
User entered 'No (N)'	System	04 Apr 2021 12:59:00

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-02T06:15:43-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '70af4e9e-0ad1-433c-b378-dd395d83c316'	System	04 Apr 2021 12:59:00
User entered 'No (N)'	System	04 Apr 2021 12:59:00

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-02T06:15:46-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '70af4e9e-0ad1-433c-b378-dd395d83c316'	System	04 Apr 2021 12:59:00
User entered '02 Apr 2021 06:15:46'	System	04 Apr 2021 12:59:00

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-09T05:11:50-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a4791524-b4d5-4717-83f9-7d18e990cc82'	System	09 Apr 2021 10:12:12
User entered 'No (N)'	System	09 Apr 2021 10:12:12

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-09T05:12:00-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a4791524-b4d5-4717-83f9-7d18e990cc82'	System	09 Apr 2021 10:12:12
User entered 'No (N)'	System	09 Apr 2021 10:12:12

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-09T05:12:08-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: 'a4791524-b4d5-4717-83f9-7d18e990cc82'	System	09 Apr 2021 10:12:12
User entered '09 Apr 2021 05:12:08'	System	09 Apr 2021 10:12:12

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-15T16:13:31-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '25d21057-af43-4e00-82a5-be957adc8ae4' User entered 'No (N)'	System	15 Apr 2021 21:13:50
	System	15 Apr 2021 21:13:50

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-15T16:13:40-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '25d21057-af43-4e00-82a5-be957adc8ae4'	System	15 Apr 2021 21:13:50
User entered 'No (N)'	System	15 Apr 2021 21:13:50

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-15T16:13:44-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '25d21057-af43-4e00-82a5-be957adc8ae4' User entered '15 Apr 2021 16:13:44'	System	15 Apr 2021 21:13:50
	System	15 Apr 2021 21:13:50

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-22T19:14:42-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8f1862fa-94ae-4ec4-812e-16a4108e0d45'	System	23 Apr 2021 00:15:11
User entered 'No (N)'	System	23 Apr 2021 00:15:11

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-22T19:15:03-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8f1862fa-94ae-4ec4-812e-16a4108e0d45'	System	23 Apr 2021 00:15:11
User entered 'No (N)'	System	23 Apr 2021 00:15:11

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-22T19:15:07-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '8f1862fa-94ae-4ec4-812e-16a4108e0d45'	System	23 Apr 2021 00:15:11
User entered '22 Apr 2021 19:15:07'	System	23 Apr 2021 00:15:11

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-29T16:41:06-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0d2be5a1-a00f-486d-bddf-f812f3273bf9' User entered 'No (N)'	System	29 Apr 2021 21:41:43
	System	29 Apr 2021 21:41:43

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

Have you been exposed to someone with 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 (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-29T16:41:33-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0d2be5a1-a00f-486d-bddf-f812f3273bf9' User entered 'No (N)'	System	29 Apr 2021 21:41:43

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-04-29T16:41:35-05:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '0d2be5a1-a00f-486d-bddf-f812f3273bf9'	System	29 Apr 2021 21:41:43
User entered '29 Apr 2021 16:41:35'	System	29 Apr 2021 21:41:43

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:54:02

US3442113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:02
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:54:02

US3442113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:43:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-28T17:59:49-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4ecf00ba-38a5-4012-800c-74e13470e774'	System	01 Mar 2021 00:00:00
User entered 'No (N)'	System	01 Mar 2021 00:00:00

US3442113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:43:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D882B4F5-075F-41C3-ABC5-DF43AAE174C1)', Time: '2021-02-28T17:59:58-06:00', User OID: 'PatientReportedOutcome (US3442113)', ODM File OID: '4ecf00ba-38a5-4012-800c-74e13470e774' User entered '28 Feb 2021 23:59:58'	System	01 Mar 2021 00:00:00
	System	01 Mar 2021 00:00:00

US3442113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:32:20
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Dec 2020 00:34:16

US3442113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:32:20
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '23 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Dec 2020 00:34:16

US3442113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:32:20
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Dec 2020 00:34:16

US3442113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:32:20
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	10 Dec 2020 00:34:16

US3442113

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
DataPoint Verified.		11 Mar 2021 20:32:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Dec 2020 00:34:23

US3442113

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:37:53
User entered 'I'	System	10 Dec 2020 00:34:23

US3442113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:32:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 22:15:38

US3442113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:32:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '14 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 22:15:38

US3442113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:32:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 22:15:38

US3442113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:32:57
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 22:15:38

US3442113

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:33:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 22:15:46

US3442113

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
User entered 'I'	System	14 Dec 2020 22:15:46

US3442113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:34:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	25 Jan 2021 19:16:02

US3442113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:34:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '25 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	25 Jan 2021 19:16:02

US3442113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:34:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	25 Jan 2021 19:16:02

US3442113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:34:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	25 Jan 2021 19:16:02

US3442113

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
DataPoint Verified.		11 Mar 2021 20:34:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	25 Jan 2021 19:16:08

US3442113

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
User entered 'I'	System	25 Jan 2021 19:16:08

US3442113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:35:19
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 20:27:47

US3442113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:35:19
User entered '23 Feb 2021'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 20:27:47

US3442113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:35:19
User entered 'Contact Made (CONTACT MADE)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 20:27:47

US3442113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:35:19
User entered empty.	Oluwatosin Akingbala (b) (4)	23 Feb 2021 20:27:47

US3442113

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:35:23
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 20:27:56

US3442113

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:40:53
User entered 'I'	System	23 Feb 2021 20:27:56

US3442113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:37:48
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:54:11

US3442113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:37:48
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered '15 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:54:11

US3442113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:37:48
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:54:11

US3442113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'VISIT4'	System	15 Mar 2021 19:54:11

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:55
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered empty.	System	30 Mar 2021 18:27:53

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34

US3442113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34

US3442113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:39:45
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:54:36

US3442113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:39:45
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:54:36

US3442113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:39:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:54:58

US3442113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:39:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered '15 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:54:58

US3442113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:39:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered '14:00'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:54:58

US3442113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered '15 Mar 2021 14:00'	System	15 Mar 2021 19:54:58

US3442113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
DataPoint Verified.		06 Apr 2021 15:39:52
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:55:06

US3442113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:40:34
User entered 'I'	System	15 Mar 2021 19:55:06

US3442113

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:29
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:26:30

US3442113

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:29
User entered '26 Apr 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:26:30

US3442113

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:26:30

US3442113

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:29
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:26:30

US3442113

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:29
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:26:37

US3442113

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 00:26:37

US3442113

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:15

US3442113

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:15

US3442113

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:15

US3442113

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 18:43:15

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:30

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:51:59

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:30

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:51:59

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:30

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:30

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 03:55:10
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	07 Jan 2021 18:43:30

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 03:55:10
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	07 Jan 2021 18:43:30

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:30

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
User entered empty.	System	07 Jan 2021 18:43:30

US3442113

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
User entered empty.	System	07 Jan 2021 18:43:30

US3442113

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:45

US3442113

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:45

US3442113

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:33:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '12:26'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:43:45

US3442113

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
User entered '7 Jan 2021 12:26'	System	07 Jan 2021 18:43:45

US3442113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:34:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:44:01

US3442113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:34:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:44:01

US3442113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
DataPoint Verified.		11 Mar 2021 20:34:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '12:22'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:44:01

US3442113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:57
User entered '7 Jan 2021 12:22'	System	07 Jan 2021 18:44:01

US3442113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:43:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:48
User closed query 'Per CDM: In Diary Dose 1, one or more symptoms are present on day 8 after dosing. Solicited adverse reactions lasting beyond 7 days post injection are to be recorded as Adverse Events. Please review and update the Adverse Events accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:42:19
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 4; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:41:34
Query 'Per CDM: In Diary Dose 1, one or more symptoms are present on day 8 after dosing. Solicited adverse reactions lasting beyond 7 days post injection are to be recorded as Adverse Events. Please review and update the Adverse Events accordingly.' answered with 'data updated' (Site from DM).	Alma Guel (b) (4)	06 Apr 2021 20:40:59
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 4; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'data updated' (Site from DM).	Alma Guel (b) (4)	06 Apr 2021 20:40:52
User opened query 'Per CDM: In Diary Dose 1, one or more symptoms are present on day 8 after dosing. Solicited adverse reactions lasting beyond 7 days post injection are to be recorded as Adverse Events. Please review and update the Adverse Events accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 22:30:27
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 4; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:26:52

US3442113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:43:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	04 Sep 2020 22:21:45
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 14:14:49

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:04
Reviewed for Safety.		07 Sep 2020 20:37:28
User entered	System	07 Sep 2020 20:35:31
'USA-US017-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 20:35:31

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:06
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' (Site from DM).		08 Mar 2021 05:59:21
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' answered with 'data updated' (Site from DM).	Alma Guel (b) (4)	05 Mar 2021 15:51:44
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Acute appendicitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:28:08
Data point term sent to Coder	System	05 Mar 2021 15:27:19
DataPoint Un-verified.	Alma Guel (b) (4)	05 Mar 2021 15:27:06
Coding entries removed.	Alma Guel (b) (4)	05 Mar 2021 15:27:06
Signature has been broken.	Alma Guel (b) (4)	05 Mar 2021 15:27:06
User entered 'ACUTE APPENDICITIS' reason for change: Data Entry Error	Alma Guel (b) (4)	05 Mar 2021 15:27:06
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:44:51
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 21:56:03

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Peritonitis, LLT: Peritonitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 17:45:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 17:45:31
Data point term sent to Coder	System	01 Dec 2020 20:03:19
DataPoint Un-verified.	Alma Guel (b) (4)	01 Dec 2020 20:02:23
Coding entries removed.	Alma Guel (b) (4)	01 Dec 2020 20:02:23
User entered 'Acute appendicitis with localized peritonitis and gangrene without perforation or abcess' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Dec 2020 20:02:23
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 22:06:58
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:24:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:24:45
Data point term sent to Coder	System	04 Sep 2020 22:23:37
User entered 'Appendicitis'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:59
User entered 'Yes (Y)'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:07:02
User entered 'No (N)'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:46
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:25:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 22:25:01
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	04 Sep 2020 22:25:01
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:07:43
DataPoint Un-verified.		18 Sep 2020 22:07:41
DataPoint Verified.		18 Sep 2020 22:07:39
User entered '2 Sep 2020'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:09:23
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 17:07:43
User entered '21:00' reason for change: Data Entry Error	Alma Guel (b) (4)	10 Nov 2020 17:07:43
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 17:01:10
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	10 Nov 2020 17:01:10
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 23:12:44
User entered '13:00' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:12:44
Query 'Data is required. Please provide.' answered with 'time unknown. records requested.' (Site from System).		08 Sep 2020 23:11:17
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Sep 2020 21:00'	System	10 Nov 2020 17:07:43
User entered empty.	System	10 Nov 2020 17:01:10
User entered '2 Sep 2020 13:00'	System	08 Sep 2020 23:12:44
User entered empty.	System	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:07:32
User entered 'No (N)'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:07:48
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Sep 2020 22:28:43
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	04 Sep 2020 22:28:43
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	04 Sep 2020 22:28:43
User entered '04 Sep 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	04 Sep 2020 22:28:43
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Sep 2020 22:22:57
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Query 'Per medical records, the discharge time is 10:51. Please update accordingly. ' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:03:47
DataPoint Verified.		10 Nov 2020 17:03:45
User entered '10:51' reason for change: Data Entry Error	Alma Guel (b) (4)	10 Nov 2020 17:01:10
User opened query 'Per medical records, the discharge time is 10:51. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:56:18
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 23:12:44
User entered '10:30' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:12:44
Query 'Data is required. Please provide.' answered with 'time unknown. records requested.' (Site from System).		08 Sep 2020 23:11:22
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 10:51'	System	10 Nov 2020 17:01:10
User entered '04 Sep 2020 10:30'	System	08 Sep 2020 23:12:44
User entered empty.	System	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:57
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:12:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:12:09
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 23:12:09
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:55
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:24:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 22:24:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	04 Sep 2020 22:24:49
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:59
User entered '0'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:00
User entered '0'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:10
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		04 Sep 2020 22:24:49
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		04 Sep 2020 22:24:49
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	04 Sep 2020 22:24:49
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	04 Sep 2020 22:22:57
User entered '0'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:08:09
User entered '3 Sep 2020'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:08:10
User entered '4 Sep 2020'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:46:32
User entered 'No (N)'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:46:30
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:46:24
User entered '0'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:46:26
User entered '0'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:46:28
User entered '0'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:43:50
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		13 Sep 2020 00:58:24
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'done' (Site from Safety).		08 Sep 2020 23:13:14
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:12:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:12:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:12:09
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		07 Sep 2020 20:32:29
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:44:00
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:12:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:12:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:12:09
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:44:06
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses please consider updating action taken to "None". If second dose was discontinued, please update action taken to Withdrawn.' (Site from Safety).		15 Sep 2020 13:27:36
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses please consider updating action taken to "None". If second dose was discontinued, please update action taken to Withdrawn.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 17:08:50
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:08:44
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses please consider updating action taken to "None". If second dose was discontinued, please update action taken to Withdrawn.' (Site from Safety).		14 Sep 2020 16:34:14
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:24:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 22:24:49
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Alma Guel (b) (4)	04 Sep 2020 22:24:49
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:22:57
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:46:14
User entered '0'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:36:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is APPENDECTOMY. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:07:30
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is APPENDECTOMY. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'corrected to match source' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 18:36:41
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 18:36:23
User entered '0' reason for change: Data Entry Error		08 Feb 2021 18:36:23
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is APPENDECTOMY. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).		20 Dec 2020 10:38:42
Query 'Medical Records states that subject was prescribed medication. Please updated all medications in the Con Meds log. ' canceled (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:25:42
User opened query 'Medical Records states that subject was prescribed medication. Please updated all medications in the Con Meds log. ' (Site from CRA).		11 Nov 2020 22:19:10
DataPoint Verified.		10 Nov 2020 16:00:07
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 17:13:46
User entered '0'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:01:46
User entered 'I'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:08:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:46:12
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:57:22
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)	07 Dec 2020 14:57:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' answered with 'sent with med records' (Site from Safety).	John Villegas (b) (4) (b) (4)	04 Dec 2020 17:37:34
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 'Sent on 01DEC2020' (Site from Safety).	John Villegas (b) (4) (b) (4)	04 Dec 2020 17:36:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 11:34:31
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).		04 Dec 2020 11:31:21

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

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)	02 Dec 2020 16:29:24
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records sent' (Site from Safety).	Alma Guel (b) (4)	01 Dec 2020 22:52:46
User closed query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider upgrading to grade 4.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:27:23
User closed query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:27:20
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:27:17
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' answered with 'please refer to redacted medical records' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:33:00
Query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' answered with 'Acute Appendicitis Focal Microscopic perforation' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:32:21
Query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider upgrading to grade 4.' answered with 'grade 3 per investigator, no change' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:21:55

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider upgrading to grade 4.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:54:36
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)	20 Nov 2020 15:54:27
User opened query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:53:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:53:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:09:27
DataPoint Un-verified.	Alma Guel (b) (4)	10 Nov 2020 17:07:43
User entered 'SUBJECT REPORTED APPENDICITIS BEGINNING ON 02SEP2020. SUBJECT CLAIMS ABDOMINAL PAIN. SUBJECT WENT TO ER ON 03SEP2020 @12:58pm AND HAD AN EMERGENCY APPENDECTOMY. RELEASED FROM HOSPITAL ON 04SEP2020 @10:51am' reason for change: Data Entry Error	Alma Guel (b) (4)	10 Nov 2020 17:07:43
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. Please leave open until resolution. ' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:11:56
User closed query ' PV Query: Please provide the pathology results of the appendix that was removed in surgery. Please leave open until resolution.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:11:44

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query ' PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable. Please leave open until resolution. ' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:11:42
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. Please leave open until resolution. ' answered with 'Multiple attempts have been made to obtain hospital records, no records have been received by site to date. Queries will continued to be answered as such by site to prevent aging of queries.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 20:22:19
Query ' PV Query: Please provide the pathology results of the appendix that was removed in surgery. Please leave open until resolution.' answered with 'Multiple attempts have been made to obtain hospital records, no records have been received by site to date. Queries will continued to be answered as such by site to prevent aging of queries.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 20:22:14
Query ' PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable. Please leave open until resolution. ' answered with 'Multiple attempts have been made to obtain hospital records, no records have been received by site to date. Queries will continued to be answered as such by site to prevent aging of queries.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 20:22:09
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. Please leave open until resolution. ' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:33:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

1979 of 2861

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

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)	23 Oct 2020 14:33:02
User opened query ' PV Query: Please provide the pathology results of the appendix that was removed in surgery. Please leave open until resolution.' (Site from Safety).		23 Oct 2020 14:32:47
User closed query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' (Site from Safety).		23 Oct 2020 14:32:47
User opened query ' PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable. Please leave open until resolution. ' (Site from Safety).		23 Oct 2020 14:32:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable. ' (Site from Safety).		23 Oct 2020 14:32:07
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 'RECORDS REQUESTED 10/3/2020' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 20:50:11
Query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' answered with 'RECORDS REQUESTED 10/3/2020' (Site from Safety).		22 Oct 2020 20:50:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable. ' answered with 'RECORDS REQUESTED 10/3/2020' (Site from Safety).		22 Oct 2020 20:49:56

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 17:35:57
User opened query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' (Site from Safety).		22 Oct 2020 17:35:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).		22 Oct 2020 17:35:33
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)	22 Oct 2020 16:53:02
User closed query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. (requested by (b) (6), issued on 17Sep2020)' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:53:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).		22 Oct 2020 16:52:59
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 'records pending. requested 10/15/2020' (Site from Safety).		21 Oct 2020 16:47:51
Query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. (requested by (b) (6), issued on 17Sep2020)' answered with 'records pending. requested 10/15/2020' (Site from Safety).		21 Oct 2020 16:47:43

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 22:08:40
DataPoint Un-verified.		18 Sep 2020 22:08:38
DataPoint Verified.		18 Sep 2020 22:08:26
User opened query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' (Site from Safety).		17 Sep 2020 12:10:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).		16 Sep 2020 14:33:54
User closed query 'PV Query: Please provide signs and symptoms for the event of appendicitis.' (Site from Safety).		16 Sep 2020 14:33:51
Query 'PV Query: Please provide signs and symptoms for the event of appendicitis.' answered with 'done' (Site from Safety).		15 Sep 2020 19:25:16
User entered 'SUBJECT REPORTED APPENDICITIS BEGINNING ON 02SEP2020. subject claims abdominal pain. SUBJECT WENT TO ER ON 03SEP2020 @ 1PM AND HAD AN EMERGENCY APPENDECTOMY. RELEASED FROM HOSPITAL ON 04SEP2020 @ 1030AM' reason for change: Data Entry Error		15 Sep 2020 19:25:10
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' answered with 'medical records requested' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 19:24:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed to diagnose/monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).		14 Sep 2020 16:34:01
User opened query 'PV Query: Please provide signs and symptoms for the event of appendicitis.' (Site from Safety).		14 Sep 2020 16:33:49

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Sep 2020 22:27:09
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Sep 2020 22:27:09
User entered 'Subject reported appendicitis beginning on 02Sep2020. Subject went to ER on 03Sep2020 @ 1pm and had an emergency appendectomy. Released from hospital on 04Sep2020 @ 1030am' reason for change: Data Entry Error	Alma Guel (b) (4)	04 Sep 2020 22:27:09
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Sep 2020 22:24:49
User entered empty.	Alma Guel (b) (4)	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 22:24:49

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Sep 2020 22:22:57

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:33:20
DataPoint Verified.		11 Mar 2021 20:36:47
User entered		08 Mar 2021 16:30:30
'USA-US017-2020-mRNA-1273-P301000001'		

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Peritonitis, LLT: Peritonitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:49:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:49:52
Data point term sent to Coder	System	05 Mar 2021 15:48:50
User entered 'LOCALIZED PERITONITIS'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'Yes (Y)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'No (N)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'No (N)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	05 Mar 2021 15:50:26
User entered '02 Sep 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	05 Mar 2021 15:50:26
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	05 Mar 2021 15:48:28
User entered '02 Sep 2021'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Mar 2021 15:50:26
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Mar 2021 15:48:28
User entered '21:00'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 21:00'	System	05 Mar 2021 15:50:26
User entered '02 Sep 2021 21:00'	System	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'No (N)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	05 Mar 2021 15:51:01
User entered '03 Sep 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	05 Mar 2021 15:51:01
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	05 Mar 2021 15:48:28
User entered '03 Sep 2021'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Mar 2021 15:50:26
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Mar 2021 15:48:28
User entered '10:51'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 10:51'	System	05 Mar 2021 15:51:01
User entered '03 Sep 2021 10:51'	System	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
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	05 Mar 2021 15:51:28
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	05 Mar 2021 15:48:28
User entered 'Yes (Y)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '0'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '0'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		05 Mar 2021 15:51:28
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		05 Mar 2021 15:51:28
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	05 Mar 2021 15:51:28
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Mar 2021 15:48:28
User entered '0'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:05
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User closed query 'PV Query: Please consider updating hospitalization dates for LOCALIZED PERITONITIS, per event narrative it states subject was hospitalized on 03 Sep 2020, however admission date provided is 02 Sep 2020, please clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:33:14
Query 'PV Query: Please consider updating hospitalization dates for LOCALIZED PERITONITIS, per event narrative it states subject was hospitalized on 03 Sep 2020, however admission date provided is 02 Sep 2020, please clarify.' answered with 'reviewed and updated. Thank you.' (Site from Safety).	Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:51:49
DataPoint Un-verified.	Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:51:33
User entered '03 Sep 2020' reason for change: Per Query Resolution	Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:51:33
User opened query 'PV Query: Please consider updating hospitalization dates for LOCALIZED PERITONITIS, per event narrative it states subject was hospitalized on 03 Sep 2020, however admission date provided is 02 Sep 2020, please clarify.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 14:56:52
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '02 Sep 2020'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:05
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Un-verified.	(b) (4)	
	Oluwatosin Akingbala	15 Mar 2021 19:51:33
	(b) (4)	
User entered '04 Sep 2020' reason for change: Per Query Resolution	Oluwatosin Akingbala	15 Mar 2021 19:51:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '03 Sep 2020'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'No (N)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered empty.	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '0'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '0'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '0'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'None (NONE)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '0'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered '0'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'I'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User entered empty.	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:36:47
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 15:49:29
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Mar 2021 15:49:29
User entered 'SUBJECT REPORTED APPENDICITIS BEGINNING ON 02SEP2020. SUBJECT CLAIMS ABDOMINAL PAIN. SUBJECT WENT TO ER ON 03SEP2020 @12:58PM AND HAD AN EMERGENCY APPENDECTOMY. RELEASED FROM HOSPITAL ON 04SEP2020 @10:51AM' reason for change: Data Entry Error	Alma Guel (b) (4)	05 Mar 2021 15:49:29
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 15:48:28
User entered empty.	Alma Guel (b) (4)	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 15:48:28

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:40:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:40:29
Data point term sent to Coder	System	06 Apr 2021 20:39:44
User entered 'fatigue'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '04 Sep 2020'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User entered empty.	System	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '09 Sep 2020'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User entered empty.	System	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'Related (RELATED)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	06 Apr 2021 20:40:35
reason for change: Data Entry Error		
User entered 'None (NONE)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'l'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:05
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User entered '0'	System	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User entered '0'	System	06 Apr 2021 20:39:24

US3442113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:48

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:48
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 09:30:40
Query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'no med taken per subject' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 22:14:21
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 18:06:54
User closed query 'Please update Flu shot details under con meds.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:38:38
Query 'Please update Flu shot details under con meds.' answered with 'updated ' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:38:20
User opened query 'Please update Flu shot details under con meds.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:23:39
DataPoint Verified.		18 Sep 2020 21:14:37

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:43:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 14:15:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: RAMIPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:22:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:22:41
Data point term sent to Coder User entered 'RAMIPRIL'	System (b) (4), (b) (6)	03 Sep 2020 14:21:12 03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	18 Sep 2020 21:21:25
User entered 'No (N)'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:26
User entered 'hypertension'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:28
User entered '10'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:30
User entered 'mg (mg)'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:21:32
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:33
User entered 'once daily (QD)'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:35
User entered empty.		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:37
User entered 'Oral (ORAL)'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:39
User entered empty.		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:40
User entered 'un UNK 2019'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:42
User entered '0'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:43
User entered 'Yes (Y)'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:45
User entered empty.		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:47
User entered 'No (N)'		03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:20:23

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:21:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: SELENIUM, PRODUCT: SELENIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:45:44
Data point term sent to Coder	System	03 Sep 2020 14:25:20
User entered 'selenium'	(b) (4), (b) (6)	03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:22:01
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:22:07
User entered 'diplopia'		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:22:10
User entered '200'		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 15:45:13
User closed query 'Doesn't match with source. Please update accordingly. ' (Site from CRA).		10 Nov 2020 15:45:12
User entered 'ug (ug)' reason for change: Data Entry Error		20 Oct 2020 16:33:19
Query 'Doesn't match with source. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:11:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:11:26
User opened query 'Doesn't match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:24:19
DataPoint Un-verified.		18 Sep 2020 21:22:25
DataPoint Verified.		18 Sep 2020 21:22:16
User closed query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		11 Sep 2020 14:58:43
Query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:22:32
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:22:11
User opened query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		10 Sep 2020 11:41:22

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 07:57:28
DataPoint Verified.		10 Nov 2020 15:45:16
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'done' (Site from DM).		20 Oct 2020 16:33:28
User entered empty; reason for change Data Entry Error		20 Oct 2020 16:33:19
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).		12 Oct 2020 11:27:08
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	01 Oct 2020 13:11:39
User entered 'mcg' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:11:39
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	01 Oct 2020 13:11:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:22:11
User entered 'mcg'		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:24:29
User entered 'once daily (QD)'		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:24:31
User entered empty.		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:24:36
User entered 'Oral (ORAL)'		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:24:39
User entered empty.		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:25:08
User entered 'un UNK 2019'		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:25:09
User entered '0'		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:25:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:25:13
User entered empty.		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:25:14
User entered 'No (N)'		03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:25:19

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:27:50
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 SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:32:46
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 Sep 2020 14:32:46
Data point term sent to Coder User entered 'singulair'	System (b) (4), (b) (6)	03 Sep 2020 14:31:37 03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:27:51
User entered 'No (N)'		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:27:53
User entered 'seasonal allergies'	(b) (4), (b) (6)	03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:27:57
User entered '10'		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:00
User entered 'mg (mg)'		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:02
User entered empty.		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:07
User entered 'once daily (QD)'		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	18 Sep 2020 21:28:08
User entered empty.		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:19
User entered 'Oral (ORAL)'		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:21
User entered empty.		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:28:24
User entered 'un UNK 2010'	(b) (4), (b) (6)	03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:27
User entered '0'		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:29
User entered 'Yes (Y)'		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:53
User entered empty.		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:28:54
User entered 'No (N)'		03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:31:35

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:29:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:34:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:34:44
Data point term sent to Coder	System	03 Sep 2020 14:33:40
User entered 'symbicort'	(b) (4), (b) (6)	03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:29:08
User entered 'No (N)'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:29:23
User entered 'asthma'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:27:18
DataPoint Verified.		10 Nov 2020 15:45:58
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'updated' (Site from DM).		05 Nov 2020 23:07:34
DataPoint Un-verified.		05 Nov 2020 23:07:26
User entered '160/4.5' reason for change: Data Entry Error		05 Nov 2020 23:07:26
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).		04 Nov 2020 18:41:32
DataPoint Verified.		18 Sep 2020 21:29:30
User entered '160'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:46:06
User closed query 'Field cannot be left empty. Please update field as "others"' (Site from CRA).		23 Oct 2020 22:00:25
User closed query 'Data is required. Please complete.' (Site from System).		12 Oct 2020 11:25:07
Query 'Field cannot be left empty. Please update field as "others"' answered with 'corrected' (Site from CRA).		08 Oct 2020 14:40:56
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	08 Oct 2020 14:40:20
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	08 Oct 2020 14:40:07
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:40:07
User opened query 'Field cannot be left empty. Please update field as "others"' (Site from CRA).		06 Oct 2020 21:07:46
DataPoint Un-verified.		06 Oct 2020 21:06:07
User closed query 'Does not match with source. Please update accordingly. ' (Site from CRA).		06 Oct 2020 21:05:36
DataPoint Verified.		06 Oct 2020 21:05:34
Query 'Data is required. Please complete.' answered with 'updated' (Site from System).	Alma Guel (b) (4)	01 Oct 2020 13:33:28
Query 'Does not match with source. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:33:16
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:31:25
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:31:25
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:30:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 14:58:57
Query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:24:23
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:24:07
User opened query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		10 Sep 2020 11:46:13
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:45:42
DataPoint Un-verified.		08 Oct 2020 14:40:20
User entered empty; reason for change Data Entry Error		08 Oct 2020 14:40:20
DataPoint Verified.		06 Oct 2020 21:05:41
User entered 'mcg' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:32:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:24:07
User entered 'mcg'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:46:36
DataPoint Un-verified.		08 Oct 2020 14:40:42
User entered 'once daily (QD)' reason for change: Data Entry Error		08 Oct 2020 14:40:42
User closed query 'Does not match with source. Please update accordingly. ' (Site from CRA).		06 Oct 2020 21:05:54
DataPoint Verified.		06 Oct 2020 21:05:50
Query 'Does not match with source. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:33:43
User entered 'other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:31:25
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:32:04
User closed query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as '2 PUFFS PER DAY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		11 Sep 2020 14:58:59
Query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as '2 PUFFS PER DAY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.'	(b) (4), (b) (6)	10 Sep 2020 13:24:32
answered with 'corrected' (Site from DM).		
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:24:07
User opened query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as '2 PUFFS PER DAY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		10 Sep 2020 11:46:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	10 Nov 2020 15:46:38
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 14:40:42
User entered empty; reason for change Data Entry Error		08 Oct 2020 14:40:42
DataPoint Verified.		06 Oct 2020 21:06:01
User closed query 'Does not match with source. Please update accordingly. ' (Site from CRA).		06 Oct 2020 21:06:00
Query 'Does not match with source. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:33:50
User entered '2 puffs QD' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:31:25
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:32:09
User entered empty; reason for change Data Entry Error		10 Sep 2020 13:24:07
User entered '2 puffs per day'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:32:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:32:16
User entered empty.		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:39:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR Re-Query: Please note the ConMed starts from UNK2010, but the corresponding MH starts from UNK 2012. Please update the ConMed start date is on or after start date of corresponding MH. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 05:10:08
Query 'Per DM CLR Re-Query: Please note the ConMed starts from UNK2010, but the corresponding MH starts from UNK 2012. Please update the ConMed start date is on or after start date of corresponding MH. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'updated. Data entry error' (Site from DM).	Alma Guel (b) (4)	01 Dec 2020 19:52:54
DataPoint Un-verified.	Alma Guel (b) (4)	01 Dec 2020 19:52:40
User entered 'UN UNK 2012' reason for change:	Alma Guel (b) (4)	01 Dec 2020 19:52:40
Data Entry Error		
User opened query 'Per DM CLR Re-Query: Please note the ConMed starts from UNK2010, but the corresponding MH starts from UNK 2012. Please update the ConMed start date is on or after start date of corresponding MH. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:58:27
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).		26 Nov 2020 06:58:27
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 'correct as entered' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 23:08:04
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).		04 Nov 2020 18:41:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:32:23
User entered 'un UNK 2010'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:32:27
User entered '0'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:32:31
User entered 'Yes (Y)'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:32:32
User entered empty.		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:32:35
User entered 'No (N)'		03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:40:42
User entered empty.	System	01 Oct 2020 13:31:25
User entered '2'	System	10 Sep 2020 13:24:07
User entered empty.	System	03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:40:42
User entered empty.	System	01 Oct 2020 13:31:25
User entered '1'	System	10 Sep 2020 13:24:07
User entered empty.	System	03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 14:40:42
User entered empty.	System	01 Oct 2020 13:31:25
User entered '804 (804)'	System	10 Sep 2020 13:24:07
User entered empty.	System	03 Sep 2020 14:33:03

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:32:45
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:35:38
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 Sep 2020 14:35:38
Data point term sent to Coder User entered 'tamsulosin'	System (b) (4), (b) (6)	03 Sep 2020 14:34:41 03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	18 Sep 2020 21:32:46
User entered 'No (N)'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:32:51
User entered 'benign prostatic hyperplasia'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 22:11:12
User closed query 'Per source, Dose per administration is listed as 0.04mg. Please reconcile with source and update accordingly. ' (Site from CRA).		05 Apr 2021 22:11:11
Query 'Per source, Dose per administration is listed as 0.04mg. Please reconcile with source and update accordingly. ' answered with 'reviewed and updated. Thank you.' (Site from CRA).	Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:32:45
Signature has been broken.	Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:32:35
User entered '0.04' reason for change: Per Query Resolution	Oluwatosin Akingbala (b) (4)	15 Mar 2021 19:32:35
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 20:42:25
DataPoint Verified.		11 Mar 2021 20:41:53
User opened query 'Per source, Dose per administration is listed as 0.04mg. Please reconcile with source and update accordingly. ' (Site from CRA).		11 Mar 2021 20:40:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate(i.e. 0.4). ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:11:01
DataPoint Un-verified.	John Villegas (b) (4)	30 Nov 2020 21:15:16
User entered '0.4' reason for change: Data Entry Error	John Villegas (b) (4)	30 Nov 2020 21:15:16
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate(i.e. 0.4). ' answered with 'updated' (Site from DM).	John Villegas (b) (4)	30 Nov 2020 21:15:09

PRODUCTION RELEASE (v12.003
EAB) (1725)

2141 of 2861

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate(i.e. 0.4). ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Nov 2020 07:02:06
		18 Sep 2020 21:32:57
User entered '0.04'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:33:00
User entered 'mg (mg)'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:33:01
User entered empty.		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:08:24
User closed query 'Does not match with source. Please update accordingly. ' (Site from CRA).		06 Oct 2020 21:08:23
Query 'Does not match with source. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:53:55
User entered 'other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:53:44
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:33:56
User closed query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		11 Sep 2020 14:59:16
Query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.'	(b) (4), (b) (6)	10 Sep 2020 13:25:30
answered with 'corrected' (Site from DM).		
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:25:21
User opened query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		10 Sep 2020 11:46:49
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:08:37
User entered 'one tab QHS' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:53:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:25:21
User entered 'once nightly'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:04
User entered 'Oral (ORAL)'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:34:05
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:08
User entered 'un UNK 2018'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:09
User entered '0'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:11
User entered 'Yes (Y)'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:13
User entered empty.		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:14
User entered 'No (N)'		03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:53:44
User entered '1'	System	10 Sep 2020 13:25:21
User entered empty.	System	03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:53:44
User entered '1'	System	10 Sep 2020 13:25:21
User entered empty.	System	03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:53:44
User entered '804 (804)'	System	10 Sep 2020 13:25:21
User entered empty.	System	03 Sep 2020 14:34:13

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:36:47
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 Sep 2020 14:36:47
Data point term sent to Coder User entered 'trazadone'	System (b) (4), (b) (6)	03 Sep 2020 14:35:42 03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:21
User entered 'No (N)'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:30:51
Query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' answered with 'recorded in med history' (Site from DM).		05 Nov 2020 23:08:52
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' (Site from DM).		04 Nov 2020 18:42:44
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:34:25
User entered 'insomnia'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:32
User entered '75'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:33
User entered 'mg (mg)'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:43
User entered empty.		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Does not match with source. Please update accordingly. ' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:09:46 06 Oct 2020 21:09:44
Query 'Does not match with source. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:55:47
User entered 'other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:55:35
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:34:49
User closed query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		11 Sep 2020 14:59:38
Query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.'	(b) (4), (b) (6)	10 Sep 2020 13:27:53
answered with 'corrected' (Site from DM).		
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:27:31
User opened query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		10 Sep 2020 11:47:05
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:09:52
User entered 'One tab QHS' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:55:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:27:31
User entered 'once nightly'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:52
User entered 'Oral (ORAL)'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	18 Sep 2020 21:34:57
User entered empty.		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:59
User entered 'un UNK 2019'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:12
User entered '0'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:14
User entered 'Yes (Y)'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:16
User entered empty.		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:35
User entered 'No (N)'		03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:55:35
User entered '1'	System	10 Sep 2020 13:27:31
User entered empty.	System	03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:55:35
User entered '1'	System	10 Sep 2020 13:27:31
User entered empty.	System	03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:55:35
User entered '804 (804)'	System	10 Sep 2020 13:27:31
User entered empty.	System	03 Sep 2020 14:34:56

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: CETRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:36:48
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 Sep 2020 14:36:48
Data point term sent to Coder User entered 'cetirizine'	System (b) (4), (b) (6)	03 Sep 2020 14:35:43 03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:44
User entered 'No (N)'		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:47
User entered 'seasonal allergies'		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:35:50
User entered '10'	(b) (4), (b) (6)	03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:52
User entered 'mg (mg)'		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:57
User entered empty.		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:36:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:09
User entered empty.		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:36:10
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:13
User entered empty.		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:17
User entered 'un Mar 2020'		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:18
User entered '0'		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:20
User entered 'Yes (Y)'		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:25
User entered empty.		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:27
User entered 'No (N)'		03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:35:39

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:39:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:39:45
Data point term sent to Coder User entered 'ambien'	System (b) (4), (b) (6)	03 Sep 2020 14:38:49 03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:42
User entered 'No (N)'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:31:04
Query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' answered with 'recorded in med history' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 23:09:14
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:43:15
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:36:46
User entered 'insomnia'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:50
User entered '2.5'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:51
User entered 'mg (mg)'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:54
User entered empty.		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:10:16
User closed query 'Does not match with source. Please update accordingly. ' (Site from CRA).		06 Oct 2020 21:10:15
Query 'Does not match with source. Please update accordingly. ' answered with 'UPDATED' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 16:58:55
User entered 'other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:56:42
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:37:04
User closed query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		11 Sep 2020 14:59:51
Query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.'	(b) (4), (b) (6)	10 Sep 2020 13:28:48
answered with 'corrected' (Site from DM).		
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:28:30
User opened query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'ONCE NIGHTLY'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).		10 Sep 2020 11:47:26
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:10:21
User entered 'One tab QHS' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:56:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:28:30
User entered 'once nightly'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:09
User entered 'Oral (ORAL)'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:11
User entered empty.		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:40:48
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 05:11:17
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'Data entry error' (Site from DM).	Alma Guel (b) (4)	01 Dec 2020 19:55:07
DataPoint Un-verified.	Alma Guel (b) (4)	01 Dec 2020 19:54:59
User entered 'UN UNK 2019' reason for change:	Alma Guel (b) (4)	01 Dec 2020 19:54:59
Data Entry Error		
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:06:41
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:37:12
User entered 'un UNK 2017'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:15
User entered '0'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:17
User entered 'Yes (Y)'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:19
User entered empty.		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	06 Oct 2020 21:10:48
User closed query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 21:10:33
Query 'Source does not indicate Y/N. Please update accordingly' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 16:59:59
User opened query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:45:38
Query 'Does not match with source. Please update accordingly. ' canceled (Site from CRA).		18 Sep 2020 21:45:33
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).		18 Sep 2020 21:40:16
DataPoint Un-verified.		18 Sep 2020 21:40:07
DataPoint Verified.		18 Sep 2020 21:37:21
User entered 'No (N)'		03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:56:42
User entered '1'	System	10 Sep 2020 13:28:30
User entered empty.	System	03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:56:42
User entered '1'	System	10 Sep 2020 13:28:30
User entered empty.	System	03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:56:42
User entered '804 (804)'	System	10 Sep 2020 13:28:30
User entered empty.	System	03 Sep 2020 14:38:01

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 21:37:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 14:39:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 14:39:43
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 14:38:49
User entered 'amlodipine'	(b) (4), (b) (6)	03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:31
User entered 'No (N)'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:37
User entered 'hypertension'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:39
User entered '2.5'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:41
User entered 'mg (mg)'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:43
User entered empty.		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:53
User entered 'once daily (QD)'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:57
User entered empty.		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:38:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:38:05
User entered empty.		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:38:07
User entered 'un UNK 2019'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:38:10
User entered '0'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:38:12
User entered 'Yes (Y)'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:38:14
User entered empty.		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	06 Oct 2020 21:11:02
User closed query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 21:11:01
Query 'Source does not indicate Y/N. Please update accordingly' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:00:22
User opened query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:45:22
Query 'Does not match with source. Please update accordingly. ' canceled (Site from CRA).		18 Sep 2020 21:45:17
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).		18 Sep 2020 21:39:57
DataPoint Un-verified.		18 Sep 2020 21:39:50
DataPoint Verified.		18 Sep 2020 21:38:16
User entered 'No (N)'		03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:38:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:38:44
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)	03 Sep 2020 14:40:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:40:40
Data point term sent to Coder User entered 'atorvastatin'	System (b) (4), (b) (6)	03 Sep 2020 14:39:53 03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:38:51
User entered 'No (N)'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:38:55
User entered 'hypercholesterolemia'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:03
User entered '10'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:06
User entered 'mg (mg)'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:11
User entered empty.		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:12
User entered 'once daily (QD)'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:14
User entered empty.		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:16
User entered 'Oral (ORAL)'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:39:18
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:20
User entered 'un UNK 2019'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:21
User entered '0'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:23
User entered 'Yes (Y)'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:39:25
User entered empty.		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:11:17
User closed query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).		06 Oct 2020 21:11:15
Query 'Source does not indicate Y/N. Please update accordingly' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:00:44
User opened query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:45:14
Query 'Does not match with source. Please update accordingly. ' canceled (Site from CRA).		18 Sep 2020 21:45:09
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).		18 Sep 2020 21:39:42
DataPoint Un-verified.		18 Sep 2020 21:39:30
DataPoint Verified.		18 Sep 2020 21:39:26
User entered 'No (N)'		03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:39:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:26:11
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' answered with 'confirmed med does not meet exclusion criteria #12' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 23:09:59
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:35:20
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:40:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: BENRALIZUMAB, PRODUCTSYNONYM: FASENRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 10:52:36
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 Sep 2020 10:52:36
Data point term sent to Coder	System	03 Sep 2020 14:40:58
User entered 'faserna'	(b) (4), (b) (6)	03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:40:47
User entered 'No (N)'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:40:51
User entered 'seasonal allergies'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:40:55
User entered '30'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:40:57
User entered 'mg (mg)'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:04
User entered empty.		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:12
User entered 'every month (QM)'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:13
User entered empty.		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:17
User entered 'Subcutaneous (SUBCUTANEOUS)'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:20
User entered empty.		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:22
User entered 'un UNK 2019'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:24
User entered '0'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:41:29
User entered 'Yes (Y)'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:42:20
User entered empty.		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:11:29
User closed query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).		06 Oct 2020 21:11:27
Query 'Source does not indicate Y/N. Please update accordingly' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:08:56
User opened query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:45:05
Query 'Does not match with source. Please update accordingly. ' canceled (Site from CRA).		18 Sep 2020 21:44:55
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).		18 Sep 2020 21:42:29
User entered 'No (N)'		03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	03 Sep 2020 14:40:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:04
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) (b) (4)	03 Sep 2020 14:42:46
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 Sep 2020 14:42:46
Data point term sent to Coder	System	03 Sep 2020 14:41:59
User entered 'levothyroxine'	(b) (4), (b) (6)	03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:43:07
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:11
User entered 'hypothyroidism'		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:13
User entered '137'		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:31:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:56:29
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).		05 Nov 2020 23:11:10
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 23:11:04
User entered 'ug (ug)' reason for change: Data Entry Error		05 Nov 2020 23:11:04
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		04 Nov 2020 18:43:55
DataPoint Verified.		18 Sep 2020 21:43:15
User entered 'mg (mg)'		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:17
User entered empty.		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:22
User entered 'once daily (QD)'		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:24
User entered empty.		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:26
User entered 'Oral (ORAL)'		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:30
User entered empty.		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:31
User entered 'un UNK 2010'		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:43:33
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:34
User entered 'Yes (Y)'		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:43:36
User entered empty.		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:11:41
User closed query 'Source does not indicate Y/N. Please update accordingly. ' (Site from CRA).		06 Oct 2020 21:11:39
Query 'Source does not indicate Y/N. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:10:09
User opened query 'Source does not indicate Y/N. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:44:27
Query 'Does not match with source. Please update accordingly. ' canceled (Site from CRA).		18 Sep 2020 21:43:55
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).		18 Sep 2020 21:43:41
User entered 'No (N)'		03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:41:21

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 11:07:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:07:32
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Nov 2020 23:13:14 05 Nov 2020 23:12:47
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:46:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:42:47
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 Sep 2020 14:42:47
Data point term sent to Coder User entered 'naproxen'	System (b) (4), (b) (6)	03 Sep 2020 14:42:02 03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:08
User entered 'No (N)'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:32:04
Query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' answered with 'recorded in med history' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 15:58:11
User entered 'GENERAL myalgias' reason for change: Data Entry Error		05 Nov 2020 23:13:08
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition 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 MedHistory eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:12:47
User entered 'general aches and pains'		05 Nov 2020 23:12:47
		04 Nov 2020 18:44:41
	(b) (4), (b) (6)	18 Sep 2020 21:46:16
		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:19
User entered '500'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:21
User entered 'mg (mg)'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:23
User entered empty.		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:25
User entered 'as needed (PRN)'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:26
User entered empty.		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:29
User entered 'Oral (ORAL)'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:31
User entered empty.		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:32
User entered 'un UNK 2019'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:33
User entered '0'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:36
User entered 'Yes (Y)'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:46:39
User entered empty.		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:11:54
User closed query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).		06 Oct 2020 21:11:52
Query 'Source does not indicate Y/N. Please update accordingly' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:10:22
User opened query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:46:46
User entered 'No (N)'		03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:41:58

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:47:42
Data point term sent to Coder User entered 'omeprazole'	System (b) (4), (b) (6)	03 Sep 2020 14:46:12 03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:25
User entered 'No (N)'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
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) (4), (b) (6)	09 Dec 2020 11:49:14
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 'correct as entered' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 23:06:05
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)	04 Nov 2020 18:46:06
DataPoint Verified.		18 Sep 2020 21:47:34
User entered 'seasonal allergies'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:38
User entered '20'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:40
User entered 'mg (mg)'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:42
User entered empty.		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:43
User entered 'as needed (PRN)'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:44
User entered empty.		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:47
User entered 'Oral (ORAL)'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:50
User entered empty.		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:54
User entered 'un UNK 2015'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:56
User entered '0'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:47:58
User entered 'Yes (Y)'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:48:01
User entered empty.		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:12:06
User closed query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).		06 Oct 2020 21:12:05
Query 'Source does not indicate Y/N. Please update accordingly' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:10:30
User opened query 'Source does not indicate Y/N. Please update accordingly' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:48:06
User entered 'No (N)'		03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:46:08

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:55:30
Query 'Does not match with the source. Please remove the log line/ make a comment as needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:55:20
User opened query 'Does not match with the source. Please remove the log line/ make a comment as needed. ' (Site from CRA).		18 Sep 2020 21:49:59
Query 'Does not match with the source. Please remove/ make a comment accordingly. ' canceled (Site from CRA).		18 Sep 2020 21:49:22
User opened query 'Does not match with the source. Please remove/ make a comment accordingly. ' (Site from CRA).		18 Sep 2020 21:49:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:47:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:47:43
Data point term sent to Coder	System	03 Sep 2020 14:47:13
User entered 'omeprazole'	(b) (4), (b) (6)	03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:55:32
User entered 'No (N)'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:55:46
User entered 'gerd'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:55:48
User entered '20'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:55:51
User entered 'mg (mg)'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:55:52
User entered empty.		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:55:56
User entered 'as needed (PRN)'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:55:57
User entered empty.		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 21:56:05
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 21:56:01
DataPoint Verified.		18 Sep 2020 21:55:58
User entered 'Oral (ORAL)'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:03
User entered empty.		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:07
User entered 'un UNK 2015'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:09
User entered '0'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:16
User entered 'Yes (Y)'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:15
User entered empty.		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:18
User entered 'No (N)'		03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:46:38

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:50:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:24:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:24:41
Data point term sent to Coder	System	08 Sep 2020 23:24:06
User entered 'ibuprofen'	(b) (4), (b) (6)	08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:50:39
User entered 'No (N)'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per ETRTR: Please consider check on Concomitant Medications within SAE "Appendicitis" page to note that SAE required ConMed, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:59:15
Query 'Per ETRTR: Please consider check on Concomitant Medications within SAE "Appendicitis" page to note that SAE required ConMed, thanks.' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:15:06
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:54:58
User opened query 'Per ETRTR: Please consider check on Concomitant Medications within SAE "Appendicitis" page to note that SAE required ConMed, thanks.' (Site from CRA).		18 Sep 2020 13:43:12
User entered 'appendectomy'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:39
User entered '400'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:42
User entered 'mg (mg)'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:56:51
User entered empty.		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:13:17
User closed query 'Does not match with source. Please update accordingly. ' (Site from CRA).		06 Oct 2020 21:13:15
Query 'Does not match with source. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:11:51
User entered 'other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 17:11:31
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:57:09
User entered 'once daily (QD)' reason for change: Data Entry Error		10 Sep 2020 13:30:16
User entered 'other (OTHER)'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:13:26
User entered 'once QHS' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 17:11:31
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 21:57:38
DataPoint Verified.		18 Sep 2020 21:57:36
User entered empty; reason for change Data Entry Error		10 Sep 2020 13:30:16
User entered 'once nightly'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:57:40
User entered 'Oral (ORAL)'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:57:41
User entered empty.		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:57:45
User entered '4 Sep 2020'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:57:46
User entered '0'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:13:38
User closed query 'Does not match with source. Please update accordingly. ' (Site from CRA).		06 Oct 2020 21:13:37
Query 'Does not match with source. Please update accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:12:24
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 17:12:15
User opened query 'Does not match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:58:05
DataPoint Un-verified.		18 Sep 2020 21:57:53
DataPoint Verified.		18 Sep 2020 21:57:47
User entered 'Yes (Y)'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:13:44
User closed query 'Please update the field accordingly. ' (Site from CRA).		06 Oct 2020 21:13:42
Query 'Please update the field accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 17:12:31
User entered '10 Sep 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 17:12:15
User opened query 'Please update the field accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:58:26
User entered empty.		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:00:23
User entered 'No (N)'		08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User entered empty.	System	01 Oct 2020 17:11:31
User entered '1'	System	10 Sep 2020 13:30:16
User entered empty.	System	08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User entered empty.	System	01 Oct 2020 17:11:31
User entered '1'	System	10 Sep 2020 13:30:16
User entered empty.	System	08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:13
User entered empty.	System	01 Oct 2020 17:11:31
User entered '804 (804)'	System	10 Sep 2020 13:30:16
User entered empty.	System	08 Sep 2020 23:23:52

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
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)	06 Feb 2021 19:36:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 19:36:02
Data point term sent to Coder	System	05 Feb 2021 12:51:46
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' canceled (Site from System).	Coder Import (b) (4)	05 Feb 2021 12:51:11
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	03 Feb 2021 10:21:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:21:50
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)	19 Nov 2020 22:00:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:00:57
Data point term sent to Coder	System	19 Nov 2020 21:59:58
User entered 'Flonase'	Tisha Davis (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:21:51
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:21:59
User entered 'Seasonal Allergies'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:06
User entered '50'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:41:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:00:52
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	01 Dec 2020 19:56:46
DataPoint Un-verified.	Alma Guel (b) (4)	01 Dec 2020 19:56:21
User entered 'ug (ug)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Dec 2020 19:56:21
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:25:44
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:22:08
User entered 'Other (OTHER)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:41:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Un-verified.	(b) (4)	
	Alma Guel (b) (4)	01 Dec 2020 19:56:21
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	01 Dec 2020 19:56:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:22:10
User entered 'mcg'	Tisha Davis (b) (4)	19 Nov 2020 21:59:10
	(b) (4)	

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:11
User entered 'once daily (QD)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:12
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:14
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:23
User entered 'un UNK 2012'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:25
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:26
User entered 'Yes (Y)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:28
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:29
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 21:59:10

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:38:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SAG 3V, PRODUCTSYNONYM: FLUAD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:37:57
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 22:37:57
Data point term sent to Coder	System	24 Nov 2020 22:36:53
User entered 'Fluad Quadrivalent'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:38:53
User entered 'Yes (Y)'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:38:54
User entered 'Flu Vaccine'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:38:56
User entered '0.5'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:38:57
User entered 'mL (mL)'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:38:58
User entered empty.	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:38:59
User entered 'once (ONCE)'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:39:02
User entered empty.	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:39:01
User entered 'Intramuscular (INTRAMUSCULAR)'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:39:04
User entered empty.	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:39:05
User entered '15 Oct 2020'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:39:06
User entered '0'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:39:07
User entered 'No (N)'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:39:09
User entered '15 Oct 2020'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:39:10
User entered 'No (N)'	Alma Guel (b) (4)	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User entered empty.	System	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User entered empty.	System	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:45
User entered empty.	System	24 Nov 2020 22:35:55

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
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/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 21:34:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:34:55
Data point term sent to Coder	System	14 Dec 2020 23:05:47
User entered 'hydrocodone-acetaminophen'	Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Pain (secondary 2 Appendectomy)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '5 - 325'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'Oral (ORAL)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '4 Sep 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '9 Sep 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
DataPoint Verified.		11 Mar 2021 20:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
User entered empty.	System	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
User entered empty.	System	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:49
User entered empty.	System	14 Dec 2020 23:05:27

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:51:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:32:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:32:19
Data point term sent to Coder	System	02 Apr 2021 16:04:46
User entered 'ondansetron'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:00
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:02
User entered 'appendicitis'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:04
User entered '4'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:06
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:09
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:12
User entered 'once (ONCE)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:14
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:16
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:17
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:18
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:20
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:21
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 14:52:23
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:24
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User entered empty.	System	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User entered empty.	System	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:54
User entered empty.	System	02 Apr 2021 16:03:51

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:42:53
Data point term sent to Coder	System	02 Apr 2021 16:13:53
User entered 'piperacillin tazobactam in dextrose'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:32
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:35
User entered 'appendicitis'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:39
User entered '4.5'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:41
User entered 'g (g)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:42
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:43
User entered 'once (ONCE)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:45
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:47
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:49
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:34
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:36
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:38
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:42
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:44
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User entered empty.	System	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User entered empty.	System	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:18
User entered empty.	System	02 Apr 2021 16:13:06

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:42:53
Data point term sent to Coder	System	02 Apr 2021 16:16:54
User entered 'piperacillin tazobactam in dextrose'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:55
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:57
User entered 'appendicitis'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:53:58
User entered '3.375'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:02
User entered 'g (g)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:03
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:11
User entered 'three times daily (TID)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:14
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:16
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:17
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:19
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:20
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:22
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:23
User entered '04 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:25
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User entered '3'	System	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User entered '1'	System	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:22
User entered '804 (804)'	System	02 Apr 2021 16:16:54

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:52
Data point term sent to Coder	System	02 Apr 2021 16:20:04
User entered 'morphine solution'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:30
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:34
User entered 'appendicitis'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:35
User entered '4'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:37
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:39
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:41
User entered 'once (ONCE)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:42
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:44
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:47
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:48
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:50
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:51
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:53
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:54
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User entered empty.	System	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User entered empty.	System	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:26
User entered empty.	System	02 Apr 2021 16:19:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:50:58
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 14:54:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 16:22:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 16:22:30
Data point term sent to Coder	System	02 Apr 2021 16:22:06
User entered 'normal saline'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:54:59
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:01
User entered 'hydration'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:03
User entered '1000'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:04
User entered 'mL (mL)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 14:55:06
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:07
User entered 'once (ONCE)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:08
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:10
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:12
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:13
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:15
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:16
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 14:55:18
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:55:19
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	02 Apr 2021 16:21:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:50:53
User closed query 'Per medical records in source, The name is IOPAMIDOL 76% (ISOVUE-370). Please change it as applicable. ' (Site from CRA).		07 Apr 2021 13:50:51
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL, PRODUCTSYNONYM: ISOVUE 370 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:29:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:29:39
Data point term sent to Coder	System	06 Apr 2021 20:29:37
Query 'Per medical records in source, The name is IOPAMIDOL 76% (ISOVUE-370). Please change it as applicable. ' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:28:52
Coding entries removed.	Alma Guel (b) (4)	06 Apr 2021 20:28:45
User entered 'IOPAMIDOL (ISOVUE-370) 76%' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:28:45
User opened query 'Per medical records in source, The name is IOPAMIDOL 76% (ISOVUE-370). Please change it as applicable. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 14:56:47
DataPoint Un-verified.		06 Apr 2021 14:55:54
DataPoint Verified.		06 Apr 2021 14:55:22
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL, PRODUCTSYNONYM: ISOVUE 370 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:09:12

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'iopamidol (isovue-370)'	Coder Import (b) (4) (b) (4) System Oluwatosin Akingbala (b) (4)	05 Apr 2021 11:09:12 02 Apr 2021 16:28:13 02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:56:49
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:57:02
User entered 'CT scan prep'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:50:56
User closed query 'Per medical records, dose is 100ml. Please refer to source and update the field as applicable' (Site from CRA).		07 Apr 2021 13:50:55
Query 'Per medical records, dose is 100ml. Please refer to source and update the field as applicable' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:29:03
User entered '100' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:28:45
User opened query 'Per medical records, dose is 100ml. Please refer to source and update the field as applicable' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 14:57:51
DataPoint Un-verified.		06 Apr 2021 14:57:08
DataPoint Verified.		06 Apr 2021 14:57:06
User entered '76'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:50:58
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:28:45
User entered 'mL (mL)' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:28:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 14:57:53
User entered 'Other (OTHER)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:51:00
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:28:45
User entered 'percent (%)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:01
User entered 'once (ONCE)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:04
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:05
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:07
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:08
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:09
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:11
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:12
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:14
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User entered empty.	System	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User entered empty.	System	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:16
User entered empty.	System	02 Apr 2021 16:27:18

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:14:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:14:02
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:23:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:54:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:54:48
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:51:17
User closed query 'Per medical records, the name is Sodium Chloride Flush Syringe. Please refer to the records and update the field as applicable. ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 13:51:15
Query 'Per medical records, the name is Sodium Chloride Flush Syringe. Please refer to the records and update the field as applicable. ' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:27:40
Data point term sent to Coder	System	06 Apr 2021 20:27:35
Coding entries removed.	Alma Guel (b) (4)	06 Apr 2021 20:27:33
User entered 'SODIUM CHLORIDE FLUSH syringe' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:27:33
User opened query 'Per medical records, the name is Sodium Chloride Flush Syringe. Please refer to the records and update the field as applicable. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 14:59:15

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 14:58:25
DataPoint Verified.		06 Apr 2021 14:58:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:59:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:59:44
Data point term sent to Coder	System	02 Apr 2021 16:30:14
User entered 'sodium chloride flush'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:18
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:21
User entered 'IV FLUSH'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:23
User entered '10'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:24
User entered 'mL (mL)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:26
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:28
User entered 'twice daily (BID)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:29
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:31
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:32
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:33
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:34
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:36
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:37
User entered '04 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:38
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User entered '2'	System	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User entered '1'	System	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:20
User entered '804 (804)'	System	02 Apr 2021 16:29:26

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:51:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:51:59
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 14:59:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:16:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:16:04
Data point term sent to Coder	System	02 Apr 2021 16:33:18
User entered 'normal saline solution'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:46
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:48
User entered 'hydration'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:53
User entered '80'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:56
User entered 'mL (mL)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:59
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:00
User entered 'other (OTHER)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:02
User entered 'continuous' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:59
User entered 'hourly'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:05
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:10
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:12
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:15
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:16
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:18
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:20
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User entered empty.	System	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User entered empty.	System	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:24
User entered empty.	System	02 Apr 2021 16:32:43

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:00:23
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/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 12:13:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 12:13:28
Data point term sent to Coder	System	02 Apr 2021 16:38:21
User entered 'hydrocodone acetaminophen'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:27
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:31
User entered 'mild pain / appendicitis'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:33
User entered '5 / 325'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:35
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:24:38
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:42
User entered 'other (OTHER)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:44
User entered 'once every 4 hours'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:46
User entered 'Oral (ORAL)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:50
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:52
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:54
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:56
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:58
User entered '04 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:00
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User entered empty.	System	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User entered empty.	System	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:29
User entered empty.	System	02 Apr 2021 16:37:32

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:39:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:39:55
Data point term sent to Coder	System	02 Apr 2021 16:47:27
User entered 'lactated ringers solution'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:24
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:26
User entered 'hydration'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:32
User entered '100'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:34
User entered 'mL (mL)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:36
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:40
User entered 'other (OTHER)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:42
User entered 'continuous'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:58
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:01
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:03
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:06
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:15
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:17
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:19
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User entered empty.	System	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User entered empty.	System	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:33
User entered empty.	System	02 Apr 2021 16:47:20

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:05:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:05:16
Data point term sent to Coder	System	02 Apr 2021 17:06:54
User entered 'hydromorphone solution'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:31
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:34
User entered 'severe pain / appendicitis'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:38
User entered '0.5'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:40
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:43
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:45
User entered 'other (OTHER)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:47
User entered 'every 5 minutes'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:49
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:50
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:52
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:54
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:56
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:58
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:00
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User entered empty.	System	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User entered empty.	System	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:38
User entered empty.	System	02 Apr 2021 17:06:05

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 17:09:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 17:09:46
Data point term sent to Coder	System	02 Apr 2021 17:08:54
User entered 'Ambien'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:07
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:09
User entered 'insomnia'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:12
User entered '5'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:17
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:18
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:20
User entered 'once (ONCE)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:21
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:23
User entered 'Oral (ORAL)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:24
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:26
User entered '04 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:27:28
User entered '0'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:51:33
User closed query 'This medication was prescribed for a month per medical records however the end date is on the same in source. And subject is current taking 2.5mg of same medication. Please clarify if the medication dosage has been increased ?' (Site from CRA).		07 Apr 2021 13:51:31
Query 'This medication was prescribed for a month per medical records however the end date is on the same in source. And subject is current taking 2.5mg of same medication. Please clarify if the medication dosage has been increased ?' answered with 'refer to PN ' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:33:19
User opened query 'This medication was prescribed for a month per medical records however the end date is on the same in source. And subject is current taking 2.5mg of same medication. Please clarify if the medication dosage has been increased ?' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:29:10
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:51:34
User entered '04 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:51:36
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User entered empty.	System	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User entered empty.	System	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:43:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:00:42
User entered empty.	System	02 Apr 2021 17:08:30

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:43:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:48
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:14:29
User closed query 'Subject experienced an AE. Please update the procedure if needed. ' (Site from CRA).		06 Oct 2020 21:14:27
Query 'Subject experienced an AE. Please update the procedure if needed. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	01 Oct 2020 13:37:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	01 Oct 2020 13:37:38
User opened query 'Subject experienced an AE. Please update the procedure if needed. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 22:09:46
User entered 'No (N)'		03 Sep 2020 14:15:30

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:14:39
User entered '3 Sep 2020'	Alma Guel (b) (4)	01 Oct 2020 13:38:25

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:02
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:59:23
DataPoint Un-verified.	Alma Guel (b) (4)	01 Dec 2020 20:52:12
User entered 'Laparoscopic APPENDECTOMY'	Alma Guel (b) (4)	01 Dec 2020 20:52:12
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:14:42
User entered 'Appendectomy'	Alma Guel (b) (4)	01 Oct 2020 13:38:25

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	23 Oct 2020 21:59:22
User closed query 'Please update the filed with indication - reason for surgery. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 21:59:05
Query 'Please update the filed with indication - reason for surgery. ' answered with 'correct as entered' (Site from CRA).		08 Oct 2020 14:45:01
User opened query 'Please update the filed with indication - reason for surgery. ' (Site from CRA).		06 Oct 2020 21:15:39
User entered 'Adverse Event (AE)'	Alma Guel (b) (4)	01 Oct 2020 13:38:25

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:11:55
User entered empty.	Alma Guel (b) (4)	01 Oct 2020 13:38:25

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:43:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 22:08:19
User entered '03 Sep 2020'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:11:34

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:43:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 22:08:20
User entered 'ct scan abdominal'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:11:34

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:43:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 22:08:22
User entered 'Diagnostic (DIAGNOSTIC)'	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:11:34

US3442113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:43:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 22:08:24
User entered empty.	Oluwatosin Akingbala (b) (4)	02 Apr 2021 17:11:34

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:41:30
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:02
DataPoint Un-verified.		18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:43
DataPoint Un-verified.		18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 22:02:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.		19 Sep 2020 08:59:38
Reviewed for Safety.		09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	11 Nov 2020 21:41:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 22:06:02
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:43
DataPoint Un-verified.		18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	06 Oct 2020 21:38:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:59:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '07/Sep/2020 16:38'	(b) (4) System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '1'		07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	11 Nov 2020 21:41:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:02
DataPoint Un-verified.		18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:43
DataPoint Un-verified.		18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 22:02:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:59:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '09/Sep/2020 13:12'	(b) (4) System	09 Sep 2020 17:12:18

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:27:50
User entered '1'		09 Sep 2020 17:12:18

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	11 Nov 2020 21:41:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:02
DataPoint Un-verified.		18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:43
DataPoint Un-verified.		18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:59:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '15/Sep/2020 09:27'	(b) (4) System	15 Sep 2020 13:28:01

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 11:56:47
User entered '1'		15 Sep 2020 13:28:01

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	11 Nov 2020 21:41:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:02
DataPoint Un-verified.		18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:43
DataPoint Un-verified.		18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.		19 Sep 2020 08:59:38
Reviewed for Safety.		09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '16/Sep/2020 07:56'	(b) (4) System	16 Sep 2020 11:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 11:59:58
User entered 'I'		16 Sep 2020 11:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:41:30
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:02
DataPoint Un-verified.		18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	06 Oct 2020 21:38:43
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.		19 Sep 2020 08:59:38
Reviewed for Safety.		09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '02/Oct/2020 08:00'	(b) (4) System	02 Oct 2020 12:00:09

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
User entered '1'		02 Oct 2020 12:00:09

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:41:30
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 22:06:02
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:43
DataPoint Un-verified.		18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:59:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '11/Nov/2020 19:41'	(b) (4) System	11 Nov 2020 19:41:43

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:29:34
User entered 'I'		11 Nov 2020 19:41:43

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	11 Nov 2020 21:41:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 22:06:02
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	06 Oct 2020 21:38:43
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:59:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '02/Dec/2020 11:29'	(b) (4) System	02 Dec 2020 16:29:45

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
User entered 'I'		02 Dec 2020 16:29:45

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	11 Nov 2020 21:41:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 22:06:02
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	06 Oct 2020 21:38:43
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.		19 Sep 2020 08:59:38
Reviewed for Safety.		09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '07/Dec/2020 10:07'	(b) (4) System	07 Dec 2020 15:07:30

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
User entered 'I'		07 Dec 2020 15:07:30

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	11 Nov 2020 21:41:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:02
DataPoint Un-verified.		18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	06 Oct 2020 21:38:43
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 22:02:58
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:59:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered '09/Feb/2021 17:33'	(b) (4) System	09 Feb 2021 17:33:19

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
Reviewed for Safety.		16 Mar 2021 14:33:51
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:19

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	11 Nov 2020 21:41:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:06:02
DataPoint Un-verified.		18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:43
DataPoint Un-verified.		18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:59:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered '08/Mar/2021 11:32'	(b) (4) System	08 Mar 2021 16:32:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:33:51
User entered 'I'		08 Mar 2021 16:32:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:41:30
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'USA-US017-2020-MRNA-1273-P301000001'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	18 Sep 2020 22:06:02
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 22:05:58
DataPoint Verified.		18 Sep 2020 22:02:16
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:43
DataPoint Un-verified.		18 Sep 2020 22:06:00
DataPoint Verified.		18 Sep 2020 22:03:07
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:38:45
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:03:15
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'Yes (Y)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 21:38:49
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:55
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:02:58
Reviewed for Safety.		07 Sep 2020 20:38:47
User entered 'No (N)'	System	07 Sep 2020 20:35:31

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:54
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'William'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'William'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	11 Nov 2020 19:41:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 21:38:56
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Seger'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Seger'		08 Sep 2020 22:19:55

US3442113

Folder: SAE-USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:23:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 13:54:22
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:41:13
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:38:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered '4505 Boat Club Road, Suite 400A'	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		25 Nov 2020 00:39:41
User closed query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).		25 Nov 2020 00:39:40
Query 'Street address is 4504 boat cub road. Please correct it' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	24 Nov 2020 22:40:36
Un-reviewed for Safety.	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	24 Nov 2020 22:40:27
User opened query 'Street address is 4504 boat cub road. Please correct it' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:11:22
DataPoint Un-verified.		24 Nov 2020 22:11:00
Reviewed for Safety.		11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:58
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '4505 Boat Club Road, Suite 400A'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '4504 Boat Club Road Suite 400A'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:38:59
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered 'Fort Worth'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Fort Worth'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:54:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:33:06
Un-reviewed for Safety.	System	02 Dec 2020 16:29:45
DataPoint Un-verified.	System	02 Dec 2020 16:29:45
User entered empty.	System	02 Dec 2020 16:29:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:29:34
DataPoint Verified.		16 Nov 2020 02:55:54
User closed query 'Please enter the state name in the field. ' (Site from CRA).		16 Nov 2020 02:55:53
Query 'Please enter the state name in the field. ' answered with 'done' (Site from CRA).		12 Nov 2020 14:38:38
Un-reviewed for Safety.		12 Nov 2020 14:38:30
User entered 'Texas' reason for change: Data Entry Error		12 Nov 2020 14:38:30
User opened query 'Please enter the state name in the field. ' (Site from CRA).		11 Nov 2020 21:43:02
Reviewed for Safety.		15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'Texas'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:41:21
DataPoint Verified.		06 Oct 2020 21:39:32
Un-reviewed for Safety.	System	02 Oct 2020 12:00:09
User entered '76135'	System	02 Oct 2020 12:00:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:27:50
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:59
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:59
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered '76135'		08 Sep 2020 22:19:55

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:39:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:59:38
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:12:01
User entered 'US' (non-conformant).	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 14:34:08
User entered '10'	System	08 Mar 2021 16:32:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:59:23
	(b) (4)	
User entered '9'	System	09 Feb 2021 17:33:19
User entered '8'	System	07 Dec 2020 15:07:30
User entered '7'	System	02 Dec 2020 16:29:45
User entered '6'	System	11 Nov 2020 19:41:43
User entered '5'	System	02 Oct 2020 12:00:09
User entered '4'	System	16 Sep 2020 11:56:59
User entered '3'	System	15 Sep 2020 13:28:01
User entered '2'	System	09 Sep 2020 17:12:18
User entered '1'	System	07 Sep 2020 20:38:53

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:43:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered '16/Mar/2021 10:34'	(b) (4) System	16 Mar 2021 14:34:08

US3442113

Folder: SAE USA-US017-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:43:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 05:10:56
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:37:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:34:08